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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re KENVUE INC. SECURITIES LITIGATION This Document Relates To: ALL CASES	Case No.: 3:23-cv-20998-ZNQ-JBD **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

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Lead Plaintiff Joseph Ditta and plaintiff David Gruthoff (collectively, "Plaintiffs"), by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief are based upon, among other things, their counsel's investigation, which includes, without limitation: (a) review and analysis of regulatory filings made by Kenvue, Inc. ("Kenvue" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases issued by Kenvue and media reports about Kenvue; (c) review and analysis of analyst reports regarding Kenvue; (d) review and analysis of other publicly available information concerning Kenvue, including transcripts of Kenvue's investor calls and conferences; and (e) review and analysis of other publicly available information. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION AND OVERVIEW

1. Plaintiffs bring this securities class action on behalf of persons and entities other than Defendants who (1) purchased or otherwise acquired shares of Kenvue common stock pursuant and/or traceable to the registration statement and related prospectus issued in connection with Kenvue's initial public offering (collectively, the "IPO Registration Statement") and suffered compensable damages caused by Defendants' violations of the Securities Act of 1933 (the "Securities Act") and/or (2) acquired shares of Kenvue common stock pursuant and/or traceable to the registration statement and related prospectus issued in connection with Johnson & Johnson's ("J&J's") August 2023 exchange offer (collectively, the "Exchange Offer Registration Statement") and suffered compensable damages caused by Defendants' violations of the Securities Act.

2. Plaintiffs' claims assert a series of strict-liability and negligence causes

of action under the Securities Act against those defendants who are statutorily responsible under Sections 11, 12(a)(2), and 15 of the Securities Act for material misstatements or omissions made in connection with the IPO and Exchange Offer.

3. Kenvue describes itself as "the world's largest pure-play consumer health company" operating at the intersection of healthcare and consumer goods. Kenvue's portfolio of brands includes many iconic names, including Tylenol, Sudafed, Benadryl, Neutrogena, Listerine, Johnson's, Band-Aid, Aveeno, Zyrtec, and Nicorette.

4. Until somewhat recently, Kenvue was J&J's consumer health segment. In November 2021, J&J announced its intention to spin off its consumer health segment as a new publicly traded company. Kenvue closed its initial public offering ("IPO") on May 8, 2023, selling 198,734,444 shares of common stock at $22 per share and raising net proceeds of $4.2 billion.

5. As of the closing of the IPO, J&J continued to control Kenvue, owning 1,716,160,000 shares of Kenvue common stock, approximately 89.6% of the total outstanding shares. On July 24, 2023, Kenvue and J&J announced an exchange offer under which J&J shareholders could exchange shares of J&J common stock for shares of Kenvue common stock owned by J&J at a discount (the "Exchange Offer"). Following the expiration of this offer on August 18, 2023, J&J exchanged 1,533,830,450 shares of Kenvue common stock in the Exchange Offer, representing approximately 80.1% of Kenvue's outstanding common stock.

6. On September 11 and 12, 2023, the Nonprescription Drugs Advisory Committee ("NDAC") of the U.S. Food and Drug Administration ("FDA") convened at the FDA's request to provide its insight and opinions as to the issue of whether orally administered phenylephrine (commonly referred to as "PE") is efficacious as a nasal decongestant, and whether oral PE should be reclassified as ***not*** Generally Recognized as Safe and Effective ("GRASE") due to lack of

efficacy.

7. Oral PE has been the most commonly used oral drug in over-the-counter ("OTC") nasal decongestants in the United States since early 2006, when restrictions on the sale of products containing pseudoephedrine were enacted due to their use in the manufacture of the illegal drug methamphetamine. Retail sales for oral PE were approximately $1.763 billion in 2022. Kenvue markets and sells numerous products containing PE, including Sudafed PE products, Benadryl Allergy Plus Congestion products, Tylenol Sinus + Headache, Tylenol Sinus Severe, and Tylenol Cold + Flu products.

8. The NDAC had previously met in December 2007 to examine the then-existing safety and efficacy data for oral PE, following concerns raised by University of Florida pharmacy professors concerning the efficacy of oral PE. At that time, the NDAC noted the inconsistency of results across then-existing studies but concluded that the available data was "suggestive" of efficacy. The NDAC, however, determined that additional clinical data would be needed to make a final decision regarding the effectiveness of oral PE.

9. After the 2007 NDAC meeting, new PE studies and trials were conducted, and the results of these studies substantially undermined the NDAC's earlier finding that the available evidence was "suggestive" of oral PE's efficacy. In November 2015, the University of Florida pharmacy professors petitioned the FDA to reconsider oral PE's efficacy in light of the new evidence. Since the submission of the November 2015 petition, additional studies and trials have further undermined the conclusion that PE is effective.

10. By the summer of 2022, two prominent associations representing pharmacists and schools of pharmacy expressed support for the FDA to remove oral PE from the FDA's monograph for OTC nasal decongestant products. In June 2022, the American College of Clinical Pharmacy submitted a public comment to

the FDA in support of the professors' November 2015 petition stating that oral PE "is ineffective at the doses employed in current over-the-counter (OTC) products available in the United States" and that these products "clearly don't work." In July 2022, the American Association of Colleges of Pharmacy likewise requested that the FDA take action to remove oral PE from the OTC market in the United States, stating that "[s]olid evidence exists and has been submitted to the FDA to support this action."

11. In or around early March 2023, the FDA announced a meeting of the NDAC scheduled for April 12, 2023, to "discuss the adequacy of efficacy data available for oral phenylephrine as a nasal decongestant and whether oral nasal decongestants phenylephrine hydrochloride and phenylephrine bitartrate should be reclassified as not 'Generally Recognized as Safe and Effective' (GRASE) due to lack of efficacy." This advisory meeting was to be one of the first test cases for the Over-the-Counter Monograph Safety, Innovation, and Reform Act, which was enacted in March 2020 and was designed to modernize the OTC drug review process and to allow the FDA to act more quickly to protect consumers from unsafe or ineffective drugs. On March 21, 2023, however, the FDA postponed this meeting to a later, undetermined date.

12. Then, on July 12, 2023, the FDA announced that the NDAC meeting would be held on September 11 and 12, 2023, to discuss the efficacy of oral phenylephrine. The FDA invited the public to comment. The September 2023 NDAC meeting ultimately considered briefings, presentations, and public comments. This included dueling briefs and presentations from the FDA and the Phenylephrine Task Group of the Consumer Healthcare Products Association

("CHPA") analyzing the available data on oral PE.[1]

13. At the conclusion of the meeting, the voting members of the NDAC panel voted unanimously that the current scientific data does not support the conclusion that orally administered PE is effective as a nasal decongestant. One member of the panel, Dr. Mark Dykewicz of the Saint Louis University School of Medicine, explained that there is "***compelling, convincing evidence that oral phenylephrine is ineffective at relieving symptoms of nasal congestion***."[2]

14. As detailed below, the registration statements and prospectuses filed by Kenvue in connection with its IPO and J&J's Exchange Offer failed to disclose the material risks that Kenvue was facing with respect to the pending regulatory proceedings before the FDA and its advisory panel to reconsider the effectiveness of oral PE. Even though there had been mounting evidence for several years that oral PE was not effective, culminating in the FDA's announcement of a meeting before the NDAC to reconsider the effectiveness of oral PE about two months before the IPO, Defendants failed to inform investors of these adverse facts. Instead, Defendants made misleading statements about the regulatory risks facing Kenvue and failed to make required disclosures in Kenvue's offering documents. While the looming NDAC meeting was a little-known fact outside of a small circle of industry insiders, it carried substantial risks for Kenvue's future prospects and should have been disclosed.

15. On the news that the NDAC unanimously voted that oral PE was not effective, Kenvue's share price fell by $1.01 per share, or 4.58%, to close at $21.06

[1] The CHPA is a national trade association that represents manufacturers and marketers of OTC medications. The Phenylephrine Task Group is comprised of nine CHPA member companies, including Kenvue, that manufacture and/or repackage OTC oral phenylephrine medications.

[2] Unless otherwise indicated, all emphasis in this Complaint has been added.

on September 12, 2021, from a prior closing price of $22.07 on September 11, 2021. Since September 12, 2021, Kenvue's shares have not gone above the $22.00 IPO price, damaging Plaintiffs and Class members.

II. JURISDICTION AND VENUE

16. The claims alleged herein arise under and pursuant to Sections 11, 12(a)(2), and 15 of the Securities Act, 15 U.S.C. §§77k, 771(a)(2) and 77o.

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 22 of the Securities Act.

18. This Court has personal jurisdiction over each of the defendants and venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 22(a) of the Securities Act (15 U.S.C. §77v(a)) as a significant portion of the Defendants' actions, and the subsequent damages took place within this District. Defendants conducted the IPO and Exchange Offer in this District, disseminated the IPO and Exchange Offer Registration Statements into this District, and Defendants solicited purchasers of shares of Kenvue common stock in this District. The Underwriter Defendants (as defined below) also have substantial operations and/or conduct substantial business in this District (directly or via agents), and represented Kenvue and all or some of the other defendants in carrying out the IPO and, as to defendants Goldman Sachs and J.P. Morgan, the Exchange Offer.

19. In connection with the acts, conduct, and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the U.S. mails, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

A. Plaintiffs

20. Lead Plaintiff Joseph Ditta, as set forth in the previously filed certification (ECF No. 18-4) incorporated by reference herein, purchased or

acquired shares of Kenvue common stock pursuant or traceable to the Company's IPO Registration Statement issued in connection with the Company's IPO, and was damaged thereby.

21. Plaintiff David Gruthoff, as set forth in the accompanying certification, acquired shares of Kenvue common stock pursuant and/or traceable to the Exchange Offer Registration Statement issued in connection with the Exchange Offer, and was damaged thereby.

B. Defendant Kenvue

22. Defendant Kenvue is incorporated under the laws of Delaware with its principal executive offices at 199 Grandview Road, Skillman, New Jersey, 08558. Following the IPO, Kenvue's common stock trades on the New York Stock Exchange (the "NYSE") under the ticker symbol "KVUE."

C. Defendant Johnson & Johnson

23. Defendant Johnson & Johnson ("J&J") is incorporated under the laws of New Jersey with its principal executive offices at One Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933. J&J common stock trades under the NYSE under the ticker symbol "JNJ."

24. Kenvue was formerly the consumer healthcare division of J&J. As of the closing of the IPO, J&J owned 1,716,160,000 shares of Kenvue common stock, or approximately 89.6% of the total outstanding shares of Kenvue common stock. As Kenvue disclosed in the IPO Registration Statement, the net proceeds from the IPO were paid to Johnson & Johnson as partial consideration for the consumer health businesses that Johnson & Johnson transferred to Kenvue. The Registration statement further explained that J&J would "continue to control the direction of [Kenvue's] business" following the IPO and that following the completion of the IPO, Kenvue would be a "controlled company" as defined under the corporate governance rules of the NYSE.

25. J&J initiated an exchange offer on July 24, 2023, under which its shareholders could exchange shares of J&J common stock for shares of Kenvue common stock owned by J&J. As a result of this exchange offer, which expired on August 18, 2023, J&J exchanged 1,533,830,450 shares of Kenvue common stock, representing approximately 80.1% of Kenvue's outstanding common stock as of August 23, 2023. Following the completion of the exchange offer, J&J owned 9.5% of the outstanding shares of Kenvue common stock.

D. The Individual Defendants

1. The Officer Defendants

26. Defendant Thibaut Mongon ("Mongon") has been Kenvue's Chief Executive Officer ("CEO") and a member of the Board of Directors since the time of the IPO. Defendant Mongon previously served as Executive Vice President and Worldwide Chairman, Consumer Health at J&J since 2019, and had been with the J&J since 2000. Defendant Mongon signed or authorized the signing on his behalf of both the Company's IPO Registration Statement and the Exchange Offer Registration Statement filed with the SEC.

27. Defendant Paul Ruh ("Ruh") has been Kenvue's Chief Financial Officer ("CFO") and a member of the Board of Directors since the time of the IPO. Defendant Ruh previously joined J&J in 2017, where he served as the CFO, Consumer Health at Johnson & Johnson since 2019. Defendant Ruh signed or authorized the signing on his behalf of both the Company's IPO Registration Statement and the Exchange Offer Registration Statement filed with the SEC.

28. Defendant Heather Howlett ("Howlett") has been Kenvue's Principal Accounting Officer since the time of the IPO. Defendant Howlett signed or authorized the signing on her behalf of both the Company's IPO Registration Statement and the Exchange Offer Registration Statement filed with the SEC.

29. Defendants Mongon, Ruh, and Howlett are sometimes collectively

referred to herein as the "Officer Defendants." Each of the Officer Defendants signed the IPO Registration Statement and Exchange Offer Registration Statement, solicited the investing public to purchase or otherwise acquire shares of common stock issued pursuant thereto, hired and assisted the underwriters, planned and contributed to the IPO, the Exchange Offer, the IPO Registration Statement, the Exchange Offer Registration Statement, and promotions to meet with and present favorable information to potential Kenvue investors, all motivated by their own and the Company's financial interests.

2. The Director Defendants

30. Defendant Larry Merlo has served as Chair of Kenvue's Board of Directors since May 2023. Defendant Merlo served as President and CEO of CVS Health from 2011 to 2021. Defendant Merlo authorized the signing on his behalf of the Exchange Offer Registration Statement filed with the SEC.

31. Defendant Richard E. Allison, Jr. has served as a member of the Board of Directors since May 2023. Defendant Allison authorized the signing on his behalf of the Exchange Offer Registration Statement filed with the SEC.

32. Defendant Peter M. Fasolo has served as a member of the Board of Directors since May 2023. Defendant Fasolo has served as Executive Vice President, Chief Human Resources Officer of J&J since 2016, and first joined J&J in 2004. Defendant Fasolo authorized the signing on his behalf of the Exchange Offer Registration Statement filed with the SEC.

33. Defendant Tamara S. Franklin has served as a member of the Board of Directors since May 2023. Defendant Franklin authorized the signing on her behalf of the Exchange Offer Registration Statement filed with the SEC.

34. Defendant Seemantini Godbole has served as a member of the Board of Directors since May 2023. Defendant Godbole authorized the signing on her behalf of the Exchange Offer Registration Statement filed with the SEC.

35. Defendant Melanie L. Healey has served as a member of the Board of Directors since May 2023. Defendant Healey has more than 30 years of experience at multinational consumer goods companies, including Procter & Gamble and J&J. Defendant Healey authorized the signing on her behalf of the Exchange Offer Registration Statement filed with the SEC.

36. Defendant Betsy D. Holden has served as a member of the Board of Directors since May 2023. Defendant Holden authorized the signing on her behalf of the Exchange Offer Registration Statement filed with the SEC.

37. Defendant Vasant Prabhu has served as a member of the Board of Directors since May 2023. Defendant Prabhu authorized the signing on his behalf of the Exchange Offer Registration Statement filed with the SEC.

38. Defendant Michael E. Sneed has served as a member of the Board of Directors since May 2023. Defendant Sneed served as Executive Vice President, Global Corporate Affairs and Chief Communication Officer of J&J and also served as a member of J&J's Executive Committee from 2018 to 2022. Defendant Sneed joined J&J in 1983 and previously held a variety of senior leadership roles. Defendant Sneed authorized the signing on his behalf of the Exchange Offer Registration Statement filed with the SEC.

39. Defendant Joseph J. Wolk has served as a member of the Board of Directors since May 2023. Defendant Wolk has served as Executive Vice President, CFO of J&J since 2018 and also serves as a member of J&J's Executive Committee. Defendant Wolk has held a variety of senior leadership roles in several sectors and functions during his 24 years at J&J. Defendant Wolk authorized the signing on his behalf of the Exchange Offer Registration Statement filed with the SEC.

40. The Defendants named in ¶¶30-39 are collectively referred to herein as the as the "Director Defendants." The Officer Defendants and the Director

Defendants are collectively referred to as the "Individual Defendants."

E. The Underwriter Defendants

41. Defendant Goldman Sachs & Co. LLC ("Goldman Sachs") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Goldman Sachs acted as a joint lead book-running manager for the IPO. Goldman Sachs agreed to purchase 43,203,140 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares. Goldman Sachs served as a dealer manager for the J&J exchange offer announced on July 24, 2023, in which J&J shareholders could exchange shares of J&J common stock for shares of Kenvue common stock.

42. Defendant J.P. Morgan Securities LLC ("J.P. Morgan") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. J.P. Morgan acted as a joint lead book-running manager for the IPO. J.P. Morgan agreed to purchase 43,203,140 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares. J.P. Morgan served as a dealer manager for the J&J exchange offer announced on July 24, 2023, in which J&J shareholders could exchange shares of J&J common stock for shares of Kenvue common stock.

43. Defendant BofA Securities, Inc. ("BofA Securities") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. BofA Securities acted as a joint lead book-running manager for the IPO. BofA Securities agreed to purchase 22,465,633 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

44. Defendant Citigroup Global Markets Inc. ("Citigroup") is an

investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Citigroup acted as a book-running manager for the IPO. Citigroup agreed to purchase 15,380,318 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

45. Defendant Deutsche Bank Securities Inc. ("Deutsche Bank") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Deutsche Bank acted as a book-running manager for the IPO. Deutsche Bank agreed to purchase 15,380,318 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

46. Defendant HSBC Securities (USA) Inc. ("HSBC") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. HSBC acted as a book-running manager for the IPO. HSBC agreed to purchase 6,221,252 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

47. Defendant RBC Capital Markets, LLC ("RBC Capital Markets" or "RBC") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. RBC acted as a book-running manager for the IPO. RBC agreed to purchase 6,221,252 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

48. Defendant BNP Paribas Securities Corp. ("BNP Paribas") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. BNP Paribas acted as a book-running manager for the IPO. BNP Paribas agreed to purchase 6,048,440 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase

additional shares.

49. Defendant UBS Securities LLC ("UBS") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO document. UBS acted as a book-running manager for the IPO. UBS agreed to purchase 5,184,377 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

50. Defendant BBVA Securities Inc. ("BBVA") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. BBVA acted as a co-manager for the IPO. BBVA agreed to purchase 1,296,094 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

51. Defendant ING Financial Markets LLC ("ING") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. ING acted as a co-manager for the IPO. ING agreed to purchase 1,296,094 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

52. Defendant Intesa Sanpaolo S.p.A ("Intesa Sanpaolo") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Intesa Sanpaolo acted as a co-manager for the IPO. Intesa Sanpaolo agreed to purchase 1,296,094 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares. Intensa Sanpaolo offered and sold any shares of Kenvue common stock in the United States through Intesa Sanpaolo IMI Securities Corp., its affiliated U.S. registered broker-dealer.

53. Defendant Santander US Capital Markets LLC ("Santander") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Santander acted as a co-

manager for the IPO. Santander agreed to purchase 1,296,094 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

54. Defendant UniCredit US Capital Markets LLC ("UniCredit") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. UniCredit acted as a co-manager for the IPO. UniCredit agreed to purchase 1,296,094 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

55. Defendant Academy Securities, Inc. ("Academy") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Academy acted as a co-manager for the IPO. Academy agreed to purchase 604,844 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

56. Defendant Independence Point Securities LLC ("Independence Point") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Independence Point acted as a co-manager for the IPO. Independence Point agreed to purchase 604,844 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

57. Defendant Samuel A. Ramirez & Company, Inc. ("Ramirez") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Ramirez acted as a co-manager for the IPO. Ramirez agreed to purchase 604,844 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

58. Defendant R. Seelaus & Co., LLC ("R. Seelaus") is an investment

banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. R. Seelaus acted as a co-manager for the IPO. R. Seelaus agreed to purchase 604,844 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

59. Defendant Siebert Williams Shank & Co., LLC ("SWS") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. SWS acted as a co-manager for the IPO. SWS agreed to purchase 604,844 shares of common stock in Kenvue's IPO, exclusive of an over-allotment option to purchase additional shares.

60. The Defendants named in ¶¶41-59 are collectively referred to herein as the "Underwriter Defendants."

61. In total, based on the underwriting discount of $0.66 per share of common stock to be paid from Kenvue to the underwriters in the IPO, and the full exercise of the Underwriter Defendants' over-allotment option, the Underwriter Defendants collectively received approximately $131,164,733.04 in connection with the IPO.

62. Pursuant to the Securities Act, the Underwriter Defendants are liable for the false and misleading statements in the Registration Statement as follows:

a. The Underwriter Defendants are investment banking houses that specialize in, *inter alia*, underwriting public offerings of securities. They served as the underwriters of the IPO and shared over $131 million in fees collectively for their services. The Underwriter Defendants determined that in return for their share of the IPO proceeds, they were willing to solicit purchases of Kenvue common stock in the IPO. The Underwriter Defendants arranged a roadshow prior to the IPO during which they, and representatives from Kenvue, met with potential investors and presented highly favorable information about the Company, its operations, and its financial prospects. Each of the Underwriter

Defendants designated personnel to the IPO working group, including investment bankers, analysts, associates, and counsel, to market shares of Kenvue's common stock, and those personnel worked on and approved the content of Kenvue's IPO Registration Statement and other offering materials.

b. The Underwriter Defendants demanded and obtained an agreement from Kenvue and the Individual Defendants that Kenvue would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws.

c. Representatives of the Underwriter Defendants also assisted Kenvue and the Individual Defendants in planning the IPO and purportedly conducted an adequate and reasonable investigation into the business and operations of Kenvue, an undertaking known as a "due diligence" investigation. The due diligence investigation was required of the Underwriter Defendants in order to engage in the IPO. During their "due diligence," the Underwriter Defendants had continual access to internal, confidential, current corporate information concerning the Company's most up-to-date operations and financial results and prospects.

d. In addition to availing themselves of virtually unlimited access to internal corporate documents, agents of the Underwriter Defendants met with Kenvue's lawyers, management, and top executives and engaged in "drafting sessions." During these sessions, understandings were reached as to: (i) the strategy to best accomplish the IPO; (ii) the terms of the IPO, including the price at which shares of Kenvue common stock would be sold; (iii) the language to be used in the IPO Registration Statement and IPO Prospectus; what disclosures about Kenvue would be made in the IPO Registration Statement and IPO Prospectus; and (iv) what responses would be made to the SEC in connection with its review of the IPO Registration Statement and IPO Prospectus. As a result of those constant

contacts and communications between the Underwriter Defendants' representatives and Kenvue's management and top executives, the Underwriter Defendants knew of, or in the exercise of reasonable care should have known of, Kenvue's existing problems as detailed herein.

e. The Underwriter Defendants caused the IPO Registration Statement and the IPO Prospectus to be filed with the SEC and declared effective in connection with the offer and sale of securities registered thereby, including those to Plaintiffs and the other members of the Class.

f. The Underwriter Defendants solicited and sold shares of Kenvue common stock to Plaintiffs and other members of the Class in the IPO. The Underwriter Defendants' failure to conduct an adequate due diligence investigation was a substantial factor leading to the harm complained of herein.

63. Kenvue, Johnson & Johnson, the Individual Defendants, and the Underwriter Defendants are referred to collectively as "Defendants."

IV. SUBSTANTIVE ALLEGATIONS

A. Background of Kenvue

64. Kenvue describes itself as "the world's largest pure-play consumer health company by revenue with $15.0 billion in net sales in 2022." The company was J&J's former consumer health segment prior to Kenvue's May 2023 IPO.

65. J&J announced its intent to spin off its consumer health segment as a new publicly traded company in November 2021. J&J explained that following the spin-off, the new consumer health company "would be a leading global consumer health company, touching the lives of over one billion consumers around the world every day through iconic brands" and that J&J would "remain the world's largest and most diverse healthcare company" by retaining its pharmaceutical and medical device segments, and would focus on "materially advancing the standard of care through biopharmaceutical and medical device innovation and technology."

66. In May 2022, J&J announced that Defendants Mongon and Ruh would be the new consumer health company's CEO Designate and CFO Designate, respectively. Defendants Mongon and Ruh had taken over the helm of J&J's consumer health segment in 2019, transforming the business and bringing significant improvements to the segment's topline and profit margins.

67. In September 2022, J&J announced that its new consumer health company would be named "Kenvue." J&J explained that the name "is inspired by two powerful ideas: 'ken' – meaning *knowledge*, an English word primarily used in Scotland, and 'vue,' referencing sight. With rich knowledge of human needs and deep consumer insights, Kenvue will deliver meaningful, personal health solutions." J&J said that the new name reflected its desire for the new consumer company's identity to take a back seat to what will be its well-known brands.

68. Defendant Mongon explained in a presentation in connection with Kenvue's roadshow[3] that "every day care is what we do and all we do" and that the Company operates in the intersection of healthcare and consumer goods, being neither a traditional CPG [consumer packaged goods] company or a traditional pharmaceutical company. Rather, Defendant Mongon explained that Kenvue excels at "delivering science backed solutions to every day needs" through its three business segments: Self Care, Skin Health and Beauty, and Essential Health:

The Company operates the business through the following three reportable business segments:

Reportable Segments	Product Categories
Self Care	Cough, Cold and Allergy
	Pain Care
	Other Self Care (Digestive Health, Smoking Cessation, and Other)
Skin Health and Beauty	Face and Body Care
	Hair, Sun and Other
Essential Health	Oral Care
	Baby Care
	Other Essential Health (Women's Health and Wound Care)

[3] Kenvue filed this transcript with the SEC on Form 425 on July 25, 2023.

69. Kenvue's portfolio of brands includes many iconic names, including Tylenol, Sudafed, Benadryl, Neutrogena, Listerine, Johnson's, Band-Aid, Aveeno, Zyrtec, and Nicorette. As such, both the investing and general public were largely familiar with many of Kenvue's products and relied on statements about the safety and efficacy of those products from both Kenvue and J&J as the prior owners of those brands and products.

B. Kenvue's IPO

70. On or about January 4, 2023, Kenvue filed with the SEC its registration statement on Form S-1, which would later be utilized in the IPO following multiple amendments on Form S-1/A, the last of which was filed on May 1, 2023, and declared effective by the SEC on May 3, 2023.

71. On May 3, 2023, J&J and Kenvue announced the pricing of the IPO at $22.00 per share of common stock. Then, on May 4, 2023, Kenvue filed with the SEC the final prospectus dated May 3, 2023 for the IPO (the "IPO Prospectus"), which forms part of the registration statement (the IPO Prospectus and the Form S-1 together with all amendments thereto, are collectively referred to as the "IPO Registration Statement").

72. On May 4, 2023, Kenvue common stock began trading on the NYSE, with the ticker symbol "KVUE."[4]

73. On May 8, 2023, the Company announced the closing of its IPO of 198,734,444 shares of its common stock at a price of $22.00 per share, including the underwriters' full exercise of their option to purchase 25,921,884 to cover over-allotments. The 198,734,444 shares of common stock sold in the IPO

[4] As part of the IPO, Kenvue, its executive officers, directors, and J&J were subject to a 180-day lock up provision, pursuant to which they could not trade their shares of Kenvue common stock, except with the prior written consent of Goldman Sachs and J.P. Morgan.

represented approximately 10.4% of Kenvue's outstanding shares, with J&J owning 1,716,160,000 shares of common stock, approximately 89.6% of the Company's outstanding shares.

74. As part of the IPO, Kenvue received approximately $4.4 billion in aggregate proceeds, and net proceeds of $4.2 billion after deducting underwriting discounts and commissions of approximately $131 million. Kenvue stated in its Prospectus that it intended to use the net proceeds from the IPO and certain debt financing transactions as partial consideration to J&J for the consumer health business that J&J transferred to Kenvue in connection with the IPO, provided that Kenvue expected to retain $1.17 billion in cash and cash equivalents to use for general corporate purposes.

C. Johnson & Johnson Exchange Offer

75. On July 24, 2023, J&J and Kenvue announced J&J's "intention to split-off at least 80.1%" of its Kenvue shares. In this announcement, J&J explained that the exchange offer would permit J&J shareholders to exchange J&J common stock for shares of Kenvue common stock at a 7% discount, subject to an upper limit of 8.0549 shares of Kenvue common stock per share of J&J common stock tendered and accepted in the exchange offer (the "Exchange Offer").[5] J&J also explained in their July 24, 2023 announcement that it would determine the prices at which shares of J&J common stock and shares of Kenvue common stock will be exchanged by referring to the arithmetic average of the daily volume-weighted average price of these two companies' shares on the NYSE during the three consecutive trading days ending on and including the second trading day

[5] J&J's July 24, 2023 announcement also stated that J&J had "received a waiver of the 180-day lock up with respect to the shares of Kenvue common stock held by it from the joint lead book-running managers of the IPO."

preceding the expiration of the exchange offer. These dates were expected to be August 14, 15, and 16, if the exchange offer was not extended or terminated.

76. In conjunction with the announcement of the Exchange Offer, on or about July 24, 2023, Kenvue filed with the SEC its registration statement on Form S-4, which would later be utilized in the Exchange Offer following an amendment on Form S-4/A, filed on August 3, 2023, and declared effective by the SEC on August 14, 2023. Also on August 14, 2023, Kenvue filed with the SEC the final prospectus dated August 14, 2023 for the Exchange Offer (the "Exchange Offer Prospectus"), which forms part of the registration statement (the Exchange Offer Prospectus and the Form S-4 together with all amendments thereto, are collectively referred to as the "Exchange Offer Registration Statement").

77. On August 16, 2023, J&J announced the final exchange ratio, stating that for each share of J&J common stock that is validly tendered and that is accepted pursuant to the exchange offer, J&J would deliver 8.0324 shares of Kenvue common stock. Then, on August 23, 2023, J&J announced the final results of its Exchange Offer, which expired at the end of the day on August 18, 2023. Pursuant to the exchange offer, J&J accepted 190,955,436 shares of J&J common stock in exchange for 1,533,830,450 shares of Kenvue common stock.

78. The Exchange Offer was oversubscribed, and thus J&J accepted only a portion of the shares of its common stock that were validly tendered on a pro rata basis of 23.23%. Shareholders who owned fewer than 100 shares of J&J common stock or an "odd-lot" and validly tendered all their shares were not subject to proration, and all these shares were accepted.

79. Following the completion of the exchange offer, J&J retained approximately 9.5% of the outstanding shares of Kenvue common stock.

D. Background Of The FDA's OTC Monograph System

80. Many of Kenvue's over-the-counter ("OTC") products marketed in the

United States are regulated by the FDA monograph system.

81. The OTC Drug Review program was created by the FDA in 1972 to facilitate the review of OTC medicines. Under the OTC monograph system, rather than approve each product, as the FDA typically does for pharmaceutical drugs, a monograph is developed for a therapeutic category. The monographs establish conditions, such as active ingredients, indications, dosage form and labeled directions, under which an OTC drug is generally recognized as safe and effective ("GRASE") for use. So long as an OTC medication meets the specific conditions contained in the monograph, it is not specifically required to be approved by the FDA before marketing. As Kenvue's IPO Registration Statement explained, "[p]roducts marketed under the OTC monograph system are required to conform to specific quality, formula and labeling requirements."

82. Under the FDA's historical OTC Drug Review Program, updating monographs could take decades due to the rulemaking process the FDA was required to follow. This slow process prevented the introduction of products that would enhance safety and convenience, as well as made it difficult for the FDA to protect patients from drugs shown to be unsafe or ineffective after approval of the original monograph.[6]

83. To address these concerns, the Over-the-Counter Monograph Safety, Innovation, and Reform Act, passed as part of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), was enacted in March 2020. With its enactment, this law was expected to make it easier for the FDA to revise

[6] *See, e.g.*, Liz Richardson, *Congress Passes Legislation to Reform Over-the-Counter Drug Regulation*, PEW TRUSTS (Mar. 27, 2020), https://www.pewtrusts.org/en/research-and-analysis/articles/2020/03/27/congress-passes-legislation-to-reform-over-the-counter-drug-regulation (last accessed Mar. 8, 2024).

monographs to reflect the latest science and respond to safety issues by allowing the FDA to regulate OTC drugs with administrative orders rather than rulemaking, placing decisions with FDA scientists, and giving the FDA a mechanism to collect data about OTC drugs in ways that help to facilitate FDA review.

E. The Regulatory History Of Oral Phenylephrine

84. In 1976, the monograph for OTC nasal decongestants was started and listed three oral drugs: phenylephrine (commonly referred to as "PE"), phenylpropanolamine, and pseudoephedrine. After an 18-year review process, the Final Monograph was released in 1994, classifying these drugs as GRASE. At the time, most OTC nasal decongestants contained either phenylpropanolamine or pseudoephedrine. However, in 2000, phenylpropanolamine was removed from the market due to its link to a risk of stroke and the FDA issued a warning against taking any product with the chemical.[7] Then, in early 2006, the Combat Methamphetamine Epidemic Act of 2005 was enacted, placing restrictions on the sale of products containing pseudoephedrine due to their use in the manufacture of the illegal drug methamphetamine. These restrictions include, for example, placing these products behind pharmacy counters or locked cabinets, requiring consumer to provide personal information every time pseudoephedrine is purchased, and/or limiting the number of purchases of products containing pseudoephedrine.

85. Although OTC products containing pseudoephedrine remain available without a prescription, it is inconvenient for a consumer to purchase. Thus, PE – which constricts blood vessels in the nasal passage – has been the main ingredient

[7] Sheryl Gay Stolberg, *Popular Cold Medicine Are Pulled From Market*, N.Y. TIMES, Nov. 7, 2000, at A1, https://www.nytimes.com/2000/11/07/us/popular-cold-medicines-are-pulled-from-market.html (last accessed Mar. 8, 2024).

pharmaceutical manufacturers have used in oral decongestants since early 2006 and accounts for four-fifths of the $2.2 billion market for oral decongestants.[8] Estimates of retail sales data from 2022 show that an "estimated 242 million bottles/packages of OTC cough/cold/allergy oral products containing PE were sold from retail stores, representing approximately 1.763 billion dollars in sales[.]"[9] Kenvue markets and sells numerous products containing PE, including Sudafed PE products, Benadryl Allergy Plus Congestion products, Tylenol Sinus + Headache, Tylenol Sinus Severe, and Tylenol Cold + Flu products.

86. In 2007, three professors from the University of Florida submitted a citizen petition requesting that the FDA amend the dosage of oral phenylephrine listed in the Final Monograph on oral decongestants and "assert[ed] that the available data do not support the adult and pediatric doses of phenylephrine hydrochloride and phenylephrine bitartrate that are generally recognized as safe and effective in the OTC drug monograph"[10] for oral decongestants.

87. In response, the FDA's Nonprescription Drug Advisory Committee

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[8] *Nasal decongestant phenylephrine, found in many over-the-counter cold and allergy medicines, doesn't work, FDA experts say*, CBS NEWS (Sept. 12, 2023), https://www.cbsnews.com/news/nasal-decongestant-phenylephrine-congestion-fda-experts/ (last accessed Mar. 8, 2024).

[9] These sales are likely underestimated because retail sales data does not capture sales from Costco, convenience or specialty stores, internet sales, or kiosks. *FDA Briefing Document: Efficacy of Oral Phenylephrine as a Nasal Decongestant*, presented as part of the Nonprescription Drug Advisory Committee Meeting held on Sept. 11 and 12, 2023, https://www.fda.gov/media/171915/download (last accessed Mar. 8, 2024).

[10] Nonprescription Drugs Advisory Committee; Notice of Meeting, 72 FR 60377 (Oct, 24, 2007), https://www.federalregister.gov/documents/2007/10/24/07-5249/nonprescription-drugs-advisory-committee-notice-of-meeting (last accessed Mar. 8, 2024).

("NDAC")[11] convened on December 14, 2007, to discuss the safety and effectiveness of oral phenylephrine as an OTC oral nasal decongestant and to address the citizen petition submitted earlier that year. Following the review of the citizen petition and the existing safety and efficacy data, the NDAC voted 11 to 1 that available evidence "is suggestive of efficacy,"[12] but recognized the limitations of the available data and "asked for new data on the absorption and efficacy of oral phenylephrine obtained using more modern standards."[13]

88. Two of the same professors from the University of Florida again submitted a citizen petition to the FDA in November 2015, asking the FDA to issue a final rule removing oral phenylephrine from the Final Monograph for OTC nasal decongestant drug products. As part of their second citizen petition, the professors cited and discussed four studies/trials reported after the December 2007 NDAC meeting that "clearly demonstrate that PE is no more effective than placebo in decreasing nasal congestions and increasing the dose fourfold did not provide additional benefit."

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[11] The FDA explains that its advisory committees, like the NDAC, "provide independent expert advice to the FDA on broad scientific topics or on certain products to help the agency make sound decisions based on the available science. Advisory committees make non-binding recommendations to the FDA, which generally follows the recommendations but is not legally bound to do so."

[12] FDA Briefing Document, *Efficacy of Oral Phenylephrine as a Nasal Decongestant*, Nonprescription Drug Advisory Committee Meeting, Sept. 11 and 12, 2023 (the "September 2023 FDA Briefing Document"), at 30, https://www.fda.gov/media/171915/download (last accessed Mar. 12, 2023).

[13] Randy Hatton, *How Two Pharmacists Figured Out That Decongestants Don't Work*, SCI. AM., Dec. 21, 2023, https://www.scientificamerican.com/article/how-two-pharmacists-figured-out-that-decongestants-dont-work/ (last accessed Mar. 8, 2024); *see also* September 2023 FDA Briefing Document at 8 ("The NDAC provided feedback that more clinical data would be needed in order to make a final decision regarding the effectiveness of oral PE"), *id.* at 30.

89. On April 21, 2016, the Consumer Healthcare Products Association ("CHPA" or the "Association")[14] Phenylephrine Task Group[15] submitted a public comment to the FDA in response to the November 2015 citizen petition, recommending that the FDA reject the request to remove oral PE from the Final Monograph for OTC nasal decongestant drug products, arguing that the studies/trials discussed in the November 2015 citizen petition had limitations and that the evidence was therefore insufficient to reverse the NDAC's prior finding that the available evidence was "suggestive" of oral PE's efficacy.

90. In May 2022, the professors submitted a supplement to their November 2015 citizen petition, citing three more studies that "support[ed] our request to have oral phenylephrine removed from monograph status." Two of these three studies cited, published in 2015 and 2017, respectively, were authored by J&J employees, and were sponsored by J&J. The May 2022 supplement concluded that the data from these J&J pharmacokinetic studies showed low concentrations of PE in plasma, which were "too low to influence the vasculature, including the nose and sinuses[,]" which "suggest[s] that doses up to three times the labeled OTC for

[14] The CHPA is a national trade association founded in 1881 and represents manufacturers and marketers of OTC medications, dietary supplementals, and consumer medical devices. The CHPA states that it is "driven by a single goal: helping people pursue happier, healthier lives through responsible self-care" by, *inter alia*, "helping regulators interpret cutting-edge science, partnering with lawmakers to craft sensible policy, or educating consumers to safely choose and use personal healthcare products." https://www.chpa.org/about-chpa (last accessed Mar. 8, 2024).

[15] The CHPA explained in a September 2023 submission to the FDA that the Phenylephrine Task Group was comprised of the nine member companies that manufacture and/or repackage OTC oral phenylephrine medications, which included Kenvue.

oral phenylephrine are unlikely to be effective as a nasal decongestant."[16]

91. In June 2022, the American College of Clinical Pharmacy submitted a public comment to the FDA in support of the November 2015 citizen petition stating that oral PE "is ineffective at the doses employed in current over-the-counter (OTC) products available in the United States" and explained that due to PE's "poor bioavailability, sufficient phenylephrine concentrations never reach the patient's systemic circulation. Hence, consumers are regularly purchasing FDA-approved products that clearly don't work." The comment concluded by imploring the FDA to remove oral PE from the monograph for OTC nasal decongestant products.

92. One month later, in July 2022, the American Association of Colleges of Pharmacy also submitted a comment to the FDA in support of the November 2015 citizen petition and requested that the FDA take action to remove oral PE from the OTC market in the United States, explaining that "[s]olid evidence exists and has been submitted to the FDA to support this action."

F. The FDA Announces An Advisory Committee Meeting To Reconsider The Efficacy Of Oral Phenylephrine

93. On or before March 3, 2023, the FDA announced on its "Advisory Committee Calendar" page of the FDA website a meeting of the NDAC for April 12, 2023 to "discuss the adequacy of efficacy data available for oral phenylephrine as a nasal decongestant and whether oral nasal decongestants phenylephrine hydrochloride and phenylephrine bitartrate should be reclassified as not 'Generally Recognized as Safe and Effective' (GRASE) due to lack of efficacy."[17]

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[16] The CHPA Phenylephrine Task Group also discussed this study in their May 2016 comment, noting that this was a pharmacokinetic study that should not be used to derive conclusions regarding PE efficacy.

[17] Archived internet images of the FDA's website are available through the Wayback Machine, which provides more than twenty-eight years of web history

94. On March 21, 2023, however, the FDA announced on this same site that the meeting scheduled for April 12, 2023 would be postponed to a later date, but did not specify the new date for the meeting. In response to the postponement of the NDAC's meeting to reconsider the efficacy of oral phenylephrine, the CHPA released a statement, saying that the CHPA was "pleased" that the FDA had postponed the NDAC's meeting, explaining that:

> Given the critical importance of this meeting on behalf of the millions of consumers who rely on this ingredient, a reasonable amount of time is needed for regulated Industry to provide a complete picture of the previously reviewed data demonstrating phenylephrine as generally recognized as safe and effective (GRASE). It is imperative that the advisory committee has access to all the data in order to provide FDA the best possible advice as the [FDA] undertakes this evaluation.[18]

95. Kenvue is a member of the CHPA, and prior to spinning off Kenvue, Johnson & Johnson was also a member. Indeed, both defendant companies play important roles in CHPA, as exemplified by the position of Michelle Wang Goodridge as Chair of the Association from on or around June 16, 2021 through on or around March 21, 2023. Ms. Goodridge is Kenvue's U.S. President of Brand Growth and was formerly the President of U.S. Self Care at the Consumer Health division of Johnson & Johnson.

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through its work archiving the Internet. *See* https://archive.org/about/ (last accessed Mar. 8, 2024).

As part of their independent investigation, Plaintiffs were able to access the FDA's advisory committee calendar through the Wayback Machine. The earliest snapshot of the announcement of the NDAC meeting was taken on March 3, 2023. *See* https://web.archive.org/web/20230303153314/https://www.fda.gov/advisory-committees/advisory-committee-calendar/april-12-2023-meeting-nonprescription-drugs-advisory-committee-meeting-announcement-04122023 (last accessed Mar. 8, 2024).

[18] https://www.chpa.org/news/2023/03/chpa-statement-fda-postponing-april-12-ndac-meeting (last accessed Mar. 8, 2024).

96. On July 12, 2023, the FDA announced that the forthcoming public advisory meeting of the NDAC to discuss the efficacy of oral phenylephrine was to be held on September 11 and 12, 2023. Specifically, the FDA announced that the September 2023 meeting was to "discuss new data regarding the 'Generally Recognized as Safe and Effective' (GRASE) status of oral phenylephrine as a nasal decongestant that have become available since FDA last examined the issue." This advisory meeting was to be one of the first test cases for the March 2020 law that overhauled the monograph system.[19] The FDA also established a docket for public comment on this meeting.

97. In anticipation of the upcoming September meeting, the CHPA released multiple statements. First, on August 23, 2023, the CHPA released the results of a recent national survey paid for by the CHPA on "consumer awareness, experiences, and perceptions of PE." The announcement explained that the survey "reveals that a majority of Americans surveyed repeatedly rely on oral PE because they recognize its efficacy as a nasal decongestant, and they experience the physical and personal benefits of oral PE when they use it."[20] Second, on September 7, 2023, the CHPA released a statement from its Vice President of Regulatory & Scientific Affairs Marcia D. Howard Ph.D., CAE, encouraging the NDAC to interpret the "totality of evidence supporting the effectiveness of oral PE" and urging the NDAC to recognize the "high acceptance and critical need for

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[19] *See, e.g.*, Lesley McClurg, *After Leading Decongestant Found Ineffective, Many Doctors Say 'Not Much' Works for Treating Common Cold*, KQED, Sept. 16, 2023, https://www.kqed.org/news/11961481/after-panel-finds-no-evidence-for-leading-drug-in-cold-meds-doctors-warn-other-remedies-also-lack-proven-effectiveness (last accessed Mar. 8, 2024).

[20] https://www.chpa.org/news/2023/08/study-consumers-use-trust-and-depend-otc-phenylephrine-pe-self-care-decongestion (last accessed Mar. 8, 2024).

consumers to have continued unrestricted access to this ingredient."[21]

98. The American Pharmacists Association ("APhA") submitted comment on August 25, 2023 to the FDA in support of the November 2015 citizen petition and expressed their support for the removal of oral PE from the Final Monograph for oral OTC nasal decongestants. The association stated that they have "tremendous experiences with OTC oral phenylephrine products" and that "patients often complain of the ineffectiveness and lack of nasal congestion relief from oral phenylephrine products." The APhA further explained that the CARES Act "modified the way OTC monograph drugs are regulated. Specifically the CARES Act replaced the standard rulemaking process with an administrative order process for issuing, revising, and amending OTC monographs. This process allows the FDA to review nonprescription drugs, like oral phenylephrine, and remove nonprescription drug products that do not meet the legal standard for OTC use." The APhA concluded that "[b]ased on the CARES Act provisions and a lack of data demonstrating the efficacy of oral phenylephrine as an OTC nasal decongestant, APhA supports removal oral phenylephrine from the Final Monograph for OTC nasal decongestant products."

99. On September 11 and 12, 2023, the NDAC met to discuss the status of oral phenylephrine. As part of this meeting, the CHPA's Phenylephrine Task Group, comprised of the nine member companies that manufacture and/or repackage OTC oral phenylephrine medications – including Kenvue, submitted both a briefing book prior to the meeting, and presented to the NDAC during the meeting. The presentation and the briefing book set forth (1) the Task Group's disagreement with the citizen petitioners' claims that new data demonstrate that PE

[21] https://www.chpa.org/news/2023/09/statement-sept-11-12-2023-meeting-fda-ndac-evaluate-efficacy-oral-pe (last accessed Mar. 8, 2024).

is not an effective nasal decongestant and (2) the Task Group's position that there were methodological limitations to the new studies and trials that made the new data unreliable. The CHPA also opined that the removal of oral PE from the monograph would have negative unintended consequences on American consumers, namely that the only other OTC treatment, *i.e.*, pseudoephedrine, has sales restrictions and is not equally available to consumers, and if pseudoephedrine were to be the only available OTC treatment, that might lead to consumers forgoing treatment of their congestion.

100. The FDA also prepared and submitted the September 2023 FDA Briefing Document with background information and analysis for the NDAC panel members and presented it during the two-day meeting. The FDA explained that it had continued to re-evaluate the scientific support for use of oral phenylephrine as a nasal decongestant since the 2007 NDAC meeting. The FDA noted that the standard for determining whether a category of OTC drugs is GRASE is set forth in 21 CFR § 330.10(a)(4)(ii), and this standard defines effectiveness as "a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed."

101. The FDA acknowledged in the briefing document that there would inevitably be a significant impact on the industry, noting that "[m]anufacturers, warehousers, and pharmacies all have a significant supply chain investment in stocks of PE, either as a precursor chemical, ingredient itself, or in a finished product. There will also be significant retooling costs." However, the FDA also cited a "number of potential benefits derived by changing the GRASE status" of oral phenylephrine, including, but not limited to:

[A]voiding the unnecessary costs and delay in care of taking a drug

> that has no benefit, avoiding the risks of potential allergic reactions or other side effects related to use of phenylephrine in combination products, avoiding the inherent risks (especially for combination therapies) of taking more in order to seek some benefit, avoiding the risks of medication use in children, lowering of overall healthcare costs, and avoiding missed opportunities for use of more effective treatments (including seeing a doctor if needed).[22]

102. Within the September 2023 FDA Briefing Document, and also during the FDA's presentation at the September meeting, the FDA summarized and evaluated the new studies and clinical trials that had been conducted since the 2007 NDAC meeting. The FDA likewise reviewed the four studies/trials that both the November 2015 citizen petition and the CHPA examined.

103. The FDA acknowledged that two of the studies, while "unacceptable as Phase 3 studies, are nevertheless acceptable when used for early Phase 2 proof-of-concept and dose finding." The FDA noted that the two studies demonstrated no efficacy for PE at monographed or slightly higher doses, and were "highly suggestive of an efficacy issue," even if they were not confirmative.[23]

104. The FDA determined that the two Merck clinical trials (also referred frequently as the Meltzer 2015 and Meltzer 2016 trials), which were both discussed in detail by the citizen petitioners and the CHPA, and a J&J trial (*see* ¶105, *infra*) used clinically acceptable designs and "represent by far the largest and most carefully constructed trials that have ever been performed to evaluate the decongestant effect of oral PE." The FDA further noted that these trials did not demonstrate any "significant difference between monographed doses of oral PE," and higher doses.[24]

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[22] September 2023 FDA Briefing Document, at 9.

[23] *Id.* at 32.

[24] *Id.*

105. The FDA also discussed and evaluated a trial conducted by J&J in Canada during the 2017-2018 cold season. This trial ended without the planned number of subjects due to the end of the cold season affecting enrollment.[25] The FDA noted that the J&J trial was the only PE study the FDA was aware of that was conducted in subjects with colds since the original panel studies were reviewed as part of the 2007 NDAC meeting. After discussing the trial and its endpoints, the FDA concluded that the J&J study's "results for all treatment arms trend in a similar direction, which suggests no beneficial effect of either PE treatment when compared with placebo."[26]

106. After thoroughly reviewing the scientific support date for the use of oral PE as a nasal decongestant, including clinical pharmacology and clinical data, as well as a detailed evaluation of the new studies and trials, the FDA concluded that in accordance with this standard of efficacy, "we have now come to the initial conclusion that orally administered PE is not effective as a nasal decongestant[.]"

G. The NDAC Committee Unanimously Votes That Oral Phenylephrine Is Not Effective

107. At the end of the two-day meeting, and after considering the presentations of the CHPA and FDA, the members of the NDAC were asked to vote yes or no to the following question: "do[es] the current scientific data that were presented support that the monographed dosage of orally administered phenylephrine is effective as a nasal decongestant?" The sixteen voting members

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[25] The CHPA also addressed the J&J study. While the CHPA acknowledged that an inference may be made from the data in this study, it noted that because the J&J study was terminated early due to the inability to recruit the planned sample size after cold season ended, it should not be considered definitive. The FDA likewise acknowledged that the J&J trial's early termination was not ideal, but nevertheless was "a much larger and better controlled than the original panel studies."

[26] September 2023 FDA Briefing Document, at 53.

of the NDAC unanimously voted "no."

108. After each member provided their vote, they were invited to provide comments. Among the comments was the following from Dr. Mark Dykewicz, Saint Louis University School of Medicine:

> I voted no. ***We now have compelling, convincing evidence that oral phenylephrine is ineffective at relieving symptoms of nasal congestion***. The evidence is derived from multiple well-designed and performed clinical trials involving large numbers of patients. These include studies in allergic rhinitis by Horak 2009, Day 2009, Meltzer 2015, Meltzer 2016, ***and in the common cold, the Johnson & Johnson sponsored trial during the 2017-2018 cold season***.

109. After each panel member had the opportunity to vote and explain their reasons for that vote, Dr. Maria Coyle, the Acting Chairperson of the NDAC, summarized the vote as follows: "FDA, I think our opinion has been shared loudly and clearly through this brief but very much aligned set of viewpoints."

H. The Market's Response To The NDAC's Determination That Phenylephrine Is Not Effective

110. Immediately after the NDAC's unanimous vote, the Wall Street Journal reported on September 12, 2023[27] that "[y]our favorite cold medicine for a stuffy nose may soon be unavailable[,]" explaining that the FDA advisory panel "declared Tuesday that an ingredient in widely used oral decongestants doesn't work, setting the stage for dozens of products to be removed from U.S. store shelves. At issue is phenylephrine, an almost-century-old ingredient in versions of Benadryl, Mucinex, Tylenol and other over-the-counter pills, syrups and liquids to clear up congested noses." The article explained that the NDAC's vote cleared the

[27] Jared S. Hopkins, *Decongestant in Cold Medicines Found Ineffective*, WALL ST. J., Sept. 12, 2023, https://www.wsj.com/health/healthcare/decongestant-cold-medicine-ineffective-f68df3f7 (last accessed Mar. 8, 2024).

way for the FDA to remove oral phenylephrine from the list of approved OTC ingredients.

111. Other news outlets were also quick to report on the NDAC's vote. For example, in a September 12, 2023 article, Bloomberg News[28] explained that if the FDA takes the NDAC's recommendation, it could begin the process of removing oral phenylephrine from the market, "forcing manufacturers, including . . . Kenvue . . . , to reformulate many popular cough and cold products."

112. The New York Times likewise reported in a September 12, 2023 article[29] that the CHPA warned that if the FDA ordered removal of products containing phenylephrine, that "numerous popular products — including Tylenol, Mucinex and Benadryl cold and flu remedies — might become unavailable as companies race to reformulate them." The September 12, 2023 New York Times article also included a quote from one of the professors who petitioned the FDA to remove oral phenylephrine from the market, Dr. Leslie Hendeles, who stated that "[i]f you have a stuffy nose and you take this medicine, you will still have a stuffy nose."

113. The New York Times article also included a quote from Dr. Maria Coyle, the chairwoman of the NDAC, stating: "I think we clearly have better

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[28] Cailley LaPara, *Common Nasal Decongestant Doesn't Actually Work, FDA Experts Say*, BLOOMBERG NEWS, Sept. 12, 2023, https://www.bloomberg.com/news/articles/2023-09-12/common-nasal-decongestant-doesn-t-work-fda-advisers-say?embedded-checkout=true (last accessed Mar. 8, 2024).

[29] Christina Jewill &Roni Caryn Rabin, *Decongestant in Cold Cures Is Ineffective, Panel Finds*, N.Y. TIMES, Sept. 12, 2023, at A21, https://www.nytimes.com/2023/09/12/health/cold-medicine-decongestant-fda.html (last accessed Mar. 8, 2024).

options in the over-the-counter space to help our patients, and the studies do not support that this is an effective drug."

114. On the news that the NDAC unanimously voted that oral phenylephrine was not effective, Kenvue's share price fell by $1.01 per share, or 4.58%, to close at $21.06 on September 12, 2021, from a prior closing price of $22.07 on September 11, 2021. Since September 12, 2021, Kenvue's shares have not gone above the $22.00 IPO price, damaging Plaintiffs and Class members. As of the market close on March 12, 2024, Kenvue's shares closed at $20.14, an 8.45% decline from the IPO price.

115. This stock price decline reflected the market's understanding that the NDAC's finding that oral PE is not effective was materially damaging to Kenvue's future prospects because, *inter alia*, (1) this finding would eliminate or severely limit Kenvue's ability to sell products containing PE as an ingredient, which would decrease future revenues associated with those products, (2) Kenvue might have to recall products already on the shelves, which could require Kenvue to accept returns from distributors and incur other costs, charges, and write-offs incident to such recalls, (3) Kenvue might have to reformulate many of its nasal decongestant products and incur costs relating to research and testing of the revised formulations, (4) Kenvue could be exposed to further regulatory action by the FDA, (5) Kenvue could be exposed to liability for false advertising, consumer fraud, and related claims for making false claims about the effectiveness of PE, and (6) Kenvue could experience reputational damage for continuing to market ineffective products after medical evidence demonstrated the ineffectiveness of those products.

116. Indeed, an October 8, 2023 Deutsche Bank report explained that "potential headwinds from voluntary decisions to reduce shipments of phenylephrine-containing products following an FDA panel's findings" and

"allowances for voluntary recalls related to phenylephrine" were among the reasons for their lowered estimates for Kenvue's third quarter and yearly financial results. Similarly, an October 31, 2023 HSBC report explained that the analysts lowered their price target to $21 from $23 for Kenvue shares due to, in part, "the potential effect of recent regulatory findings surrounding the (in)effectiveness of oral phenylephrine creat[ing] additional uncertainty around prospects."

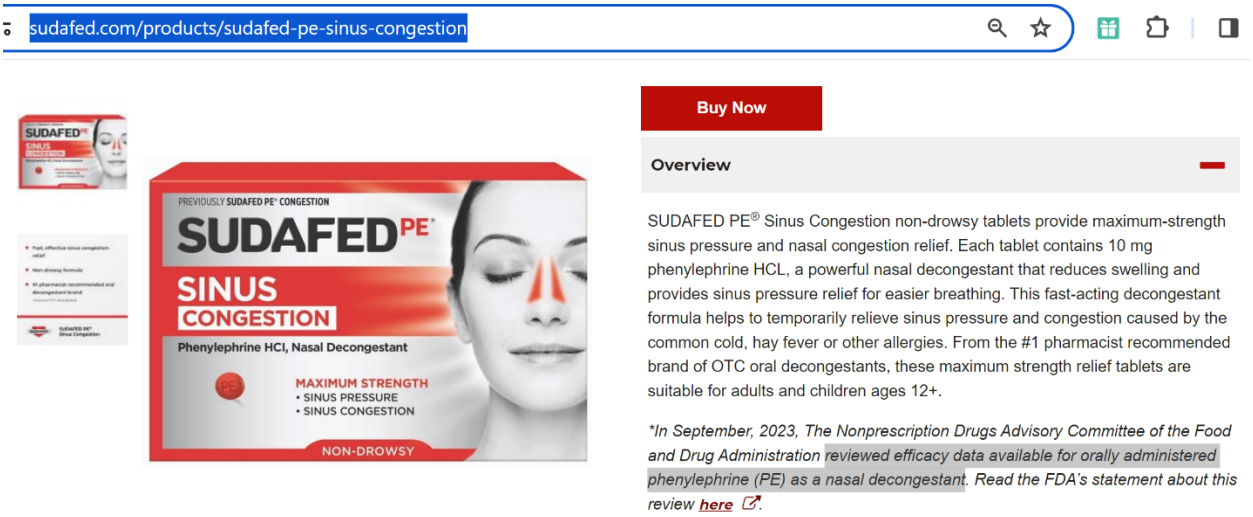
117. A number of these negative consequences have already begun to materialize. On or around October 19, 2023, news outlets began reporting that CVS decided to voluntarily remove from its shelves oral decongestants that contain PE as the only active ingredient.

118. In its annual report for the fiscal year ended December 31, 2023 and filed with the SEC on Form 10-K on March 1, 2024, Kenvue reported that following the NDAC vote, "putative class actions were filed against the Company and its affiliates, along with other sellers and manufacturers of PE-containing products, asserting various causes of action including violation of consumer protection statutes, negligence, and unjust enrichment. Separately, putative Canadian class actions were filed beginning in September 2023 against our affiliates, along with other sellers and manufacturers of PE-containing products, alleging false, misleading representations, and seeking damages and declaratory relief based on similar causes of action."

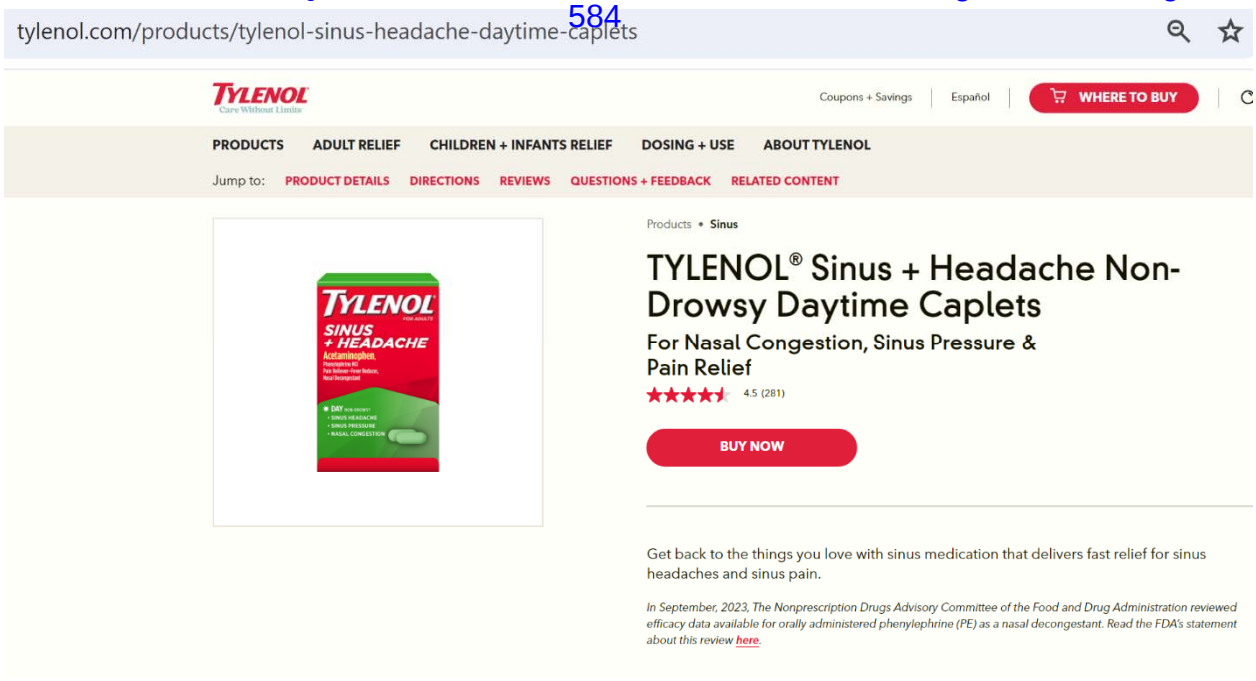
119. Despite the NDAC's unanimous vote and these subsequent lawsuits, the Company still extols the benefits of its oral PE products on the product's packaging, while containing only limited disclosure on these products' websites about the NDAC's determination about the efficacy of oral PE.

120. For example, as of March 8, 2024, Kenvue still advertises Sudafed PE Sinus Congestion product as a "maximum strength" or "powerful" nasal decongestant, and that "[t]his fact-acting decongestant formula helps to

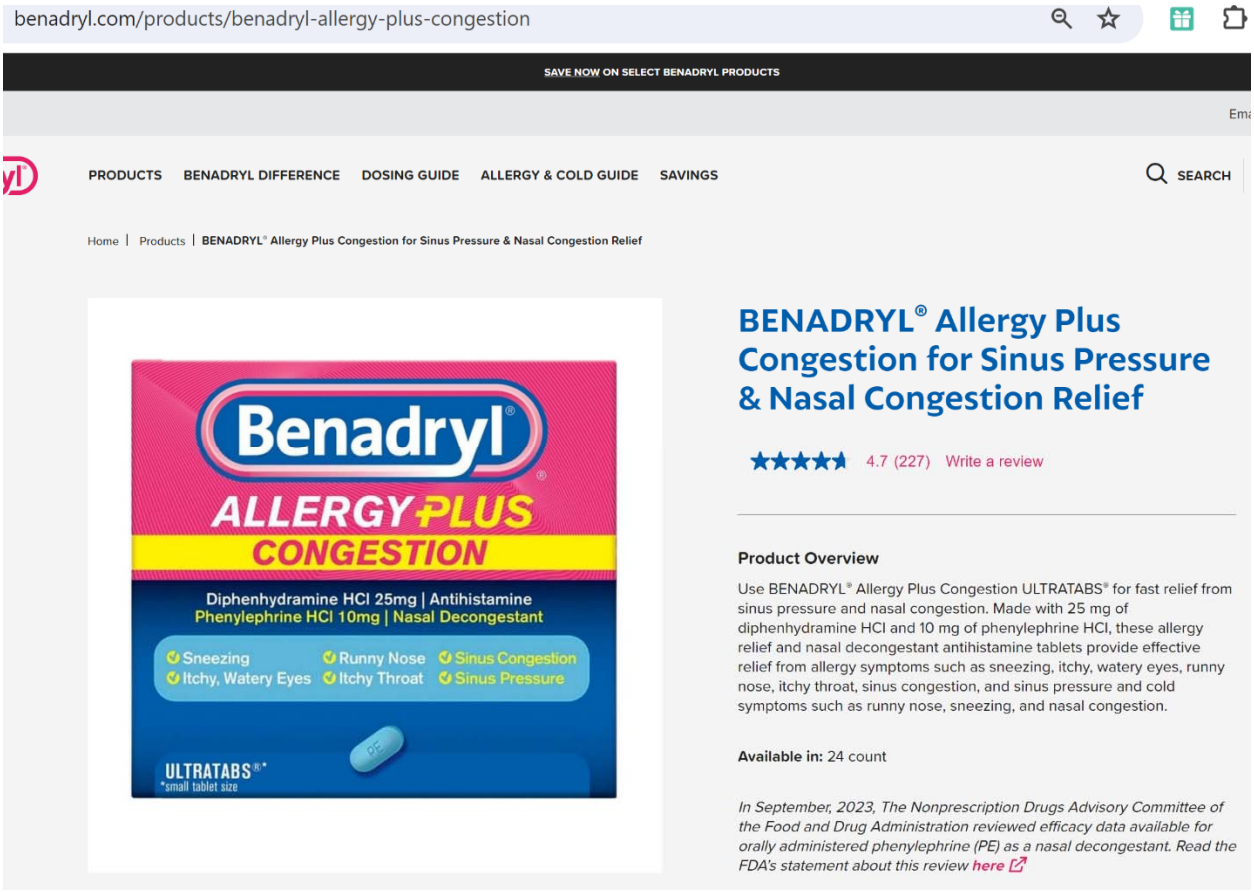
temporarily relieve sinus pressure and congestion caused by the common cold, hay fever or other allergies." While the Sudafed website notes that the NDAC "reviewed efficacy data available for orally administered phenylephrine (PE) as a nasal decongestant" in September 2023 and links to the FDA's statement about such review, nowhere on the packaging is such disclosure displayed:



121. Likewise, as of March 8, 2024, Kenvue advertises advertises Tylenol Sinus + Headache Non-Drowsy Daytime Caplets as providing "fast relief" for sinus headaches and sinus pain, while providing the same limited disclosure on its product's website about the NDAC's "review of efficacy data" of oral PE as a nasal decongestant:



122. Kenvue similarly advertises Benadryl Allergy Plus Congestion as providing "fast" and "effective" relief from sinus pressure and nasal congestion as of March 8, 2024, while again providing the same limited disclosure on its product's website about the NDAC's "review of efficacy data" of oral PE as a nasal decongestant:



V. KENVUE'S REGISTRATION STATEMENT CONTAINED MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS AND FAILED TO MAKE REQUIRED DISCLOSURES UNDER ITEM 105 OF SEC REGULATION S-K

123. The IPO Registration Statement and the Exchange Offer Registration Statement were negligently prepared and, as a result, contained untrue statements of material fact or omitted to state material facts necessary to make the statements contained therein not misleading, and failed to make necessary disclosures required under the rules and regulations governing their preparation, specifically including Item 105 of SEC Regulation S-K.

A. The IPO Registration Statement And Prospectus

124. On or about January 4, 2023, Kenvue filed with the SEC a registration statement on Form S-1, which would later be utilized in the IPO following multiple

amendments on Form S-1/A. Kenvue filed the first amendment to the registration statement on February 3, 2023, the second amendment to the registration statement on March 3, 2023, the third amendment to the registration statement on March 30, 2023, the fourth amendment to the registration statement on April 24, 2023, and the fifth and final amendment to the registration statement on May 1, 2023. The amended registration statement was declared effective by the SEC on May 3, 2023. The final IPO prospectus was filed on May 4, 2023, but was dated May 3, 2023.

125. For the purposes of the following paragraphs (¶¶126-133), the quoted statements are derived from the fourth amendment to the registration statement filed on April 24, 2023, which contain language that is identical to the language in the final prospectus filed on May 4, 2023.[30] Earlier versions of the registration statement contained either identical or nearly identical versions of the same statements, but the final and effective versions of the statements were contained in the fourth amendment to the registration statement filed on April 24, 2023 and the final prospectus filed on May 4, 2023, which are reflected in the paragraphs below.

126. In the Risk Factors section of the IPO Registration Statement and the IPO Prospectus, the Company stated that "[c]oncerns about the reliability, safety or efficacy of our products or their ingredients could result in litigation, regulatory action, reputational damage, product recalls, product reformulations or product withdrawals, which could adversely affect our business, results of operations or

[30] The fifth amendment to the registration statement filed on May 1, 2023 was filed solely for the purpose of filing certain exhibits and therefore consisted only of the facing page, an explanatory note, Part II of the Registration Statement, the signature page, and the filed exhibits. The fifth amendment to the registration statement did not include a preliminary prospectus, which had been included within the previously-filed versions of the registration statement. The final language of the preliminary prospectus, therefore, was reflected in the fourth amendment to the registration statement filed on April 24, 2023.

financial condition." In detailing this risk, the Company stated:

> ***Concerns about the reliability, safety or efficacy of our products or their ingredients, whether raised internally or by litigants, regulators, consumer advocacy groups, third-party interest groups or others, and whether or not based on scientific or factual evidence, have resulted, and could in the future result, in governmental investigations, regulatory action (including the shutdown of manufacturing facilities), private claims and lawsuits, significant remediation and related costs, safety alerts, product shortages, declining sales or reputational damage (including damage to brand image, brand equity and consumer trust in our products)***. . . .
>
> Product recalls, product reformulations and product withdrawals of various magnitudes have occurred in each of our business segments and may occur in the future, including as a result of manufacturing issues, contamination issues, shipping and other supply chain issues and labeling issues. . . .
>
> We have also faced, and could face in the future, concerns about the reliability, safety or efficacy of the ingredients used in our products. Scrutiny of ingredients we use in our products, including scrutiny that originates on digital or social media platforms, may result in an inability to use, or restrictions on the use of, the ingredients or a requirement for remedial action, which could cause us to incur significant additional costs, particularly if we need or otherwise decide to reformulate the affected products, or result in litigation. . . .
>
> If we remove certain ingredients from our products, either voluntarily or pursuant to a regulatory mandate, we may not be able to successfully develop an alternative formulation or obtain necessary regulatory approvals on a timely basis, or at all. Furthermore, any reformulated product we introduce to the market may not be positively received by consumers and customers, which could result in lost sales, damage our reputation or our brands or otherwise adversely affect our business, results of operations or financial condition.
>
> Moreover, negative perceptions of our products or their ingredients may arise from product liability claims, product recalls or product withdrawals, regardless of whether the claims, recalls or withdrawals directly involve us or our products. In addition, the mere publication

> of information asserting concerns about the reliability, safety or efficacy of competing products or ingredients in competing products that are also used in our products could adversely affect our business, results of operations or financial condition. Increased regulation, litigation or adverse publicity concerning ingredients used in our products, such as acetaminophen, may discourage consumers from buying our products that contain those ingredients, even when the regulation, litigation or publicity does not directly relate to or expressly mention us or our products, and even if not accurate. In addition, ***we believe our products are reliable, safe and effective when used for their intended purposes in accordance with label directions***. However, consumers have misused, and may in the future misuse, our products, including for unauthorized, nefarious or other unintended purposes, which in certain instances has had, and may in the future have, serious or even fatal implications. Misuse of our products has led to, and may in the future lead to, criticism on digital and social media platforms, negative coverage by traditional media and other forms of adverse publicity regarding our products or their ingredients, which could similarly discourage consumers from buying our products or otherwise adversely affect our reputation or our brands.

127. The foregoing statements in ¶126 were materially false and/or misleading because they failed to disclose, *inter alia*, the following adverse facts that existed at the time of the Kenvue IPO:

(a) Substantial concerns had been raised about the effectiveness of products containing PE for more than a decade, and those concerns proved to be well-founded;

(b) Between 2007 and 2023, multiple well-designed studies and clinical trials involving large numbers of patients demonstrated that oral PE is ineffective at relieving symptoms of sinus and nasal congestion. These studies and trials included studies in allergic rhinitis by Horak 2009 and Day 2009, trials in subjects with seasonal allergic rhinitis by Meltzer 2015 and Meltzer 2016, and in the common cold, a Johnson

& Johnson sponsored trial during the 2017-2018 cold season;

(c) In November 2015, two University of Florida professors submitted a citizen petition to the FDA asking the FDA to issue a final rule removing oral PE from the Final Monograph for OTC nasal decongestant drugs and citing four studies demonstrating, *inter alia*, that PE "is no more effective than placebo in decreasing nasal congestions and increasing the dose fourfold did not provide additional benefit";

(d) In May 2022, the professors submitted a supplement to their November 2015 citizen petition, citing three additional studies, including two studies sponsored by Johnson & Johnson, one of which suggested that "doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant";

(e) In June 2022, the American College of Clinical Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition stating that oral PE "is ineffective at the doses employed in current over-the-counter (OTC) products available in the United States" and explaining that due to PE's "poor bioavailability, sufficient phenylephrine concentrations never reach the patient's systemic circulation. Hence, consumers are regularly purchasing FDA-approved products that clearly don't work";

(f) In July 2022, the American Association of Colleges of Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition and requested the FDA to take action to remove oral PE from the OTC market in the United States, explaining that "[s]olid evidence exists and has been submitted to the FDA to support this action";

(g) On or before March 3, 2023, the FDA announced a meeting of the NDAC for April 12, 2023 to "discuss the adequacy of efficacy data available for oral phenylephrine as a nasal decongestant and whether oral nasal decongestants phenylephrine hydrochloride and phenylephrine bitartrate should be reclassified as not 'Generally Recognized as Safe and Effective' (GRASE) due to lack of efficacy";

(h) Roughly six weeks before the Kenvue IPO, on March 21, 2023, the FDA announced that this meeting would be postponed to a later unspecified date;

(i) As a result of the foregoing, Kenvue's asserted belief that its products "are reliable, safe and effective when used for their intended purposes in accordance with label directions" lacked a reasonable basis, at least with respect to Kenvue's products containing oral PE as an ingredient to treat sinus and nasal congestion, and Defendants' statement failed to disclose facts that seriously undermined the supposed basis for Kenvue's asserted belief;

(j) As a result of the foregoing, regulatory action by the FDA and its NDAC panel was probable and imminent, and the failure to disclose the pendency of these proceedings and the underlying studies demonstrating the ineffectiveness of oral PE caused investors to materially underestimate the risks that Kenvue faced with respect to its products containing PE as an ingredient; and

(k) Defendants' statement that "[c]oncerns about the reliability, safety or efficacy of our products . . . have resulted, and could in the future result, in governmental investigations, regulatory action . . . , private claims and lawsuits, . . . [or] declining sales or reputational damage" was materially misleading because it failed to disclose that significant

> regulatory proceedings under the new OTC monograph had already been initiated by the FDA with respect to the efficacy of oral PE. Therefore, the risk of regulatory action with respect to oral PE, including the risk that there would be a determination that oral PE was not effective, was substantially heightened, and Defendants' statement failed to disclose material facts necessary to appreciate the magnitude of the risk.

128. The IPO Registration Statement and the IPO Prospectus touted the strength of the Company's brands and the efficacy of its products. While the IPO Registration Statement and the IPO Prospectus made no mention of phenylephrine (or PE) by name, they did make the following statement about Kenvue's full line of Tylenol products, which includes Tylenol products containing PE:

> Tylenol is the #1 global Pain brand and the #2 global Self Care brand, with the #1 U.S. household penetration. Tylenol has been caring for families since 1955 when its first product, Children's Elixir, was launched. Although the Tylenol story started with just one product, it has evolved to include a full suite of pain relief, cold and flu, sleep and pediatric products. ***Studies sponsored by Johnson & Johnson Consumer Inc. and by third parties have shown that these products help relieve, among other things***, headache and muscle pain, arthritis pain, ***sinus and nasal congestion***, fever and pain with sleeplessness. We are continuously looking for ways to expand Tylenol's brand leadership, particularly through our digital and connected health offerings. For example, in 2022 we launched the Tylenol SmartCheck Digital Ear Scope, which empowers consumers to work with their healthcare providers to check for ear infections remotely, avoiding costly and time-consuming in-person visits.

129. The foregoing statements in ¶128 were materially false and/or misleading because they failed to disclose, *inter alia*, the following adverse facts that existed at the time of the Kenvue IPO:

(a) Substantial concerns had been raised about the effectiveness of

products containing PE for more than a decade, and those concerns proved to be well-founded;

(b) Between 2007 and 2023, multiple well-designed studies and clinical trials involving large numbers of patients demonstrated that oral PE is ineffective at relieving symptoms of sinus and nasal congestion. These studies and trials included studies in allergic rhinitis by Horak 2009 and Day 2009, trials in subjects with seasonal allergic rhinitis by Meltzer 2015 and Meltzer 2016, and in the common cold, a Johnson & Johnson sponsored trial during the 2017-2018 cold season;

(c) In November 2015, two University of Florida professors submitted a citizen petition to the FDA asking the FDA to issue a final rule removing oral PE from the Final Monograph for OTC nasal decongestant drugs and citing four studies demonstrating, *inter alia*, that PE "is no more effective than placebo in decreasing nasal congestions and increasing the dose fourfold did not provide additional benefit";

(d) In May 2022, the professors submitted a supplement to their November 2015 citizen petition, citing three additional studies, including two studies sponsored by Johnson & Johnson, one of which suggested that "doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant";

(e) In June 2022, the American College of Clinical Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition stating that oral PE "is ineffective at the doses employed in current over-the-counter (OTC) products available in the United States" and explaining that due to PE's "poor bioavailability, sufficient phenylephrine concentrations never reach the patient's systemic

circulation. Hence, consumers are regularly purchasing FDA-approved products that clearly don't work";

(f) In July 2022, the American Association of Colleges of Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition and requested the FDA to take action to remove oral PE from the OTC market in the United States, explaining that "[s]olid evidence exists and has been submitted to the FDA to support this action";

(g) On or before March 3, 2023, the FDA announced a meeting of the NDAC for April 12, 2023 to "discuss the adequacy of efficacy data available for oral phenylephrine as a nasal decongestant and whether oral nasal decongestants phenylephrine hydrochloride and phenylephrine bitartrate should be reclassified as not 'Generally Recognized as Safe and Effective' (GRASE) due to lack of efficacy";

(h) Roughly six weeks before the Kenvue IPO, on March 21, 2023, the FDA announced that this meeting would be postponed to a later unspecified date;

(i) As a result of the foregoing, Defendants' statement that "[s]tudies sponsored by Johnson & Johnson . . . and by third parties have shown that these products help relieve . . . sinus and nasal congestion" was materially false and misleading and lacked a reasonable basis, at least with respect to Tylenol products containing PE, including Tylenol Sinus + Headache, Tylenol Sinus Severe, and Tylenol Cold + Flu products, and Defendants' statement failed to disclose facts that seriously undermined the veracity and basis of this statement; and

(j) As a result of the foregoing, regulatory action by the FDA and its NDAC panel was probable and imminent, and the failure to disclose

the pendency of these proceedings and the underlying studies demonstrating the ineffectiveness of oral PE caused investors to materially underestimate the risks that Kenvue faced with respect to its products containing PE as an ingredient.

130. The IPO Registration Statement and the IPO Prospectus made the following statement concerning the FDA's OTC monograph system:

> In order to market and sell a new drug product in the United States, a manufacturer must (1) file a New Drug Application ("NDA") that shows the quality, safety and effectiveness of the new drug, (2) file an Abbreviated New Drug Application that demonstrates the equivalence of a generic product to another company's branded drug product or (3) comply with the FDA's monograph system. Most of our OTC products marketed in the United States, including Aveeno Restorative Skin Therapy Itch Relief Balm, Neutrogena Invisible Daily Defense, Tylenol Dissolve Packs, certain of our Listerine mouthwash products and certain products intended to treat acne or be used as sunscreen, including skin care products with SPF, are regulated pursuant to the FDA's monograph system. The monographs establish the conditions, such as active ingredients, uses (indications), doses, labeling and testing, under which an OTC drug is generally recognized as safe and effective and can be marketed without an NDA and FDA premarket approval. ***Products marketed under the OTC monograph system are required to conform to specific quality, formula and labeling requirements. OTC monograph products that do not comply with these standards can be deemed unapproved new drugs and can be required to be withdrawn from the market. The Over-the-Counter Monograph Safety, Innovation, and Reform Act, enacted in March 2020, is expected to introduce significant reform to the OTC monograph system, including by replacing the FDA's existing rulemaking process with an administrative order process for issuing, revising and amending OTC monographs***.

131. The foregoing statements in ¶130 were materially false and/or misleading because they failed to disclose, *inter alia*, the following adverse facts that existed at the time of the Kenvue IPO:

(a) Substantial concerns had been raised about the effectiveness of

products containing PE for more than a decade, and those concerns proved to be well-founded;

(b) Between 2007 and 2023, multiple well-designed studies and clinical trials involving large numbers of patients demonstrated that oral PE is ineffective at relieving symptoms of sinus and nasal congestion. These studies and trials included studies in allergic rhinitis by Horak 2009 and Day 2009, trials in subjects with seasonal allergic rhinitis by Meltzer 2015 and Meltzer 2016, and in the common cold, a Johnson & Johnson sponsored trial during the 2017-2018 cold season;

(c) In November 2015, two University of Florida professors submitted a citizen petition to the FDA asking the FDA to issue a final rule removing oral PE from the Final Monograph for OTC nasal decongestant drugs and citing four studies demonstrating, *inter alia*, that PE "is no more effective than placebo in decreasing nasal congestions and increasing the dose fourfold did not provide additional benefit";

(d) In May 2022, the professors submitted a supplement to their November 2015 citizen petition, citing three additional studies, including two studies sponsored by Johnson & Johnson, one of which suggested that "doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant";

(e) In June 2022, the American College of Clinical Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition stating that oral PE "is ineffective at the doses employed in current over-the-counter (OTC) products available in the United States" and explaining that due to PE's "poor bioavailability, sufficient phenylephrine concentrations never reach the patient's systemic

circulation. Hence, consumers are regularly purchasing FDA-approved products that clearly don't work";

(f) In July 2022, the American Association of Colleges of Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition and requested the FDA to take action to remove oral PE from the OTC market in the United States, explaining that "[s]olid evidence exists and has been submitted to the FDA to support this action";

(g) On or before March 3, 2023, the FDA announced a meeting of the NDAC for April 12, 2023 to "discuss the adequacy of efficacy data available for oral phenylephrine as a nasal decongestant and whether oral nasal decongestants phenylephrine hydrochloride and phenylephrine bitartrate should be reclassified as not 'Generally Recognized as Safe and Effective' (GRASE) due to lack of efficacy";

(h) Roughly six weeks before the Kenvue IPO, on March 21, 2023, the FDA announced that this meeting would be postponed to a later unspecified date;

(i) The forthcoming meeting convened by the FDA requesting that the NDAC review, discuss, and vote on the efficacy of oral PE as a nasal decongestant was to be one of the first test cases for the March 2020 law that overhauled the monograph system;

(j) As a result of the foregoing, Defendants' statements concerning the requirements of and reforms to the OTC monograph system were materially misleading because they failed to disclose that regulatory proceedings under the newly reformed monograph system had already been initiated with the express purpose of reconsidering the efficacy of oral PE as a nasal decongestant, that these proceedings were to be

the first of their kind under the newly reformed system, and that these proceedings carried a high risk of a determination that oral PE was not effective;

(k) As a result of the foregoing, regulatory action by the FDA and its NDAC panel was probable and imminent, and the failure to disclose the pendency of these proceedings and the underlying studies demonstrating the ineffectiveness of oral PE caused investors to materially underestimate the risks that Kenvue faced with respect to its products containing PE as an ingredient.

132. Item 105 of Regulation S-K requires that offering documents "provide under the caption 'Risk Factors' a discussion of the material factors that make an investment in the registrant or offering speculative or risky." 17 C.F.R. § 229.105(a). Item 105 further requires the offering documents to "[c]oncisely explain how each risk affects the registrant or the securities being offered." 17 C.F.R. § 229.105(b). The discussion of risk factors:

> must be specific to the particular company and its operations, and should explain how the risk affects the company and/or the securities being offered. Generic or boilerplate discussions do not tell the investors how the risks may affect their investment.

Statement of the Comm'n Regarding Disclosure of Year 2000 Issues and Consequences by Pub. Cos., Inv. Advisers, Inv. Cos., & Mun. Sec. Issuers, 1998 WL 425894, at *14 (July 29, 1998).

133. Here, Defendants failed to adequately disclose, and in fact did not disclose at all, in the "Risk Factors" section of the IPO Registration Statement and the IPO Prospectus, the risks to Kenvue's sales, revenue, prospects, reputation and potential liability in relation to its line of products containing oral PE as an ingredient to treat sinus or nasal congestion. While the IPO Registration Statement and the IPO Prospectus did disclose hypothetical risks concerning the safety,

reliability or efficacy of Kenvue's general range of products (and specific disclosures concerning past or pending issues related to certain products other than its products containing PE),[31] they did not disclose any specific risks relating to Kenvue's products containing PE and they failed to disclose specific facts necessary for investors to understand the magnitude of the risk, including the FDA's initiation of regulatory proceedings, with requested input from the NDAC, concerning the efficacy of oral PE. These PE-specific risks were material to Kenvue's sales, revenue, prospects, reputation and potential liability, *see supra* at ¶115, and should have been disclosed.

B. The Exchange Offer Registration Statement

134. On or about July 24, 2023, Kenvue filed with the SEC its registration statement on Form S-4, which would later be utilized in the Exchange Offer following an amendment on Form S-4/A, filed on August 3, 2023 and declared effective by the SEC on August 14, 2023. Also, on August 14, 2023, Kenvue filed with the SEC the final prospectus for the Exchange Offer dated August 14, 2023, which forms part of the registration statement.

135. For the purposes of the following paragraphs (¶¶136-143), the quoted language is identical in each of the Form S-4 filed on July 24, 2023, the Form S-4/A filed on August 3, 2023, and the final prospectus formed on August 14, 2023.

136. In the Risk Factors section of the Exchange Offer Registration Statement and the Exchange Offer Prospectus, the Company stated that "[c]oncerns about the reliability, safety or efficacy of Kenvue's products or their ingredients could result in litigation, regulatory action, reputational damage,

[31] Certain of Kenvue's Tylenol products contain both acetaminophen and PE, but the risk disclosure at issue only discussed risks related to safety concerns about acetaminophen, not risks related to efficacy concerns about PE.

product recalls, product reformulations or product withdrawals, which could adversely affect Kenvue's business, results of operations or financial condition." In In detailing this risk, the Company stated:

> ***Concerns about the reliability, safety or efficacy of Kenvue's products or their ingredients, whether raised internally or by litigants, regulators, consumer advocacy groups, third-party interest groups or others, and whether or not based on scientific or factual evidence, have resulted, and could in the future result, in governmental investigations, regulatory action (including the shutdown of manufacturing facilities), private claims and lawsuits, significant remediation and related costs, safety alerts, product shortages, declining sales or reputational damage (including damage to brand image, brand equity and consumer trust in Kenvue's products)***. . . .
>
> Product recalls, product reformulations and product withdrawals of various magnitudes have occurred in each of Kenvue's business segments and may occur in the future, including as a result of manufacturing issues, contamination issues, shipping and other supply chain issues and labeling issues. . . .
>
> Kenvue has also faced, and could face in the future, concerns about the reliability, safety or efficacy of the ingredients used in Kenvue's products. Scrutiny of ingredients Kenvue uses in its products, including scrutiny that originates on digital or social media platforms, may result in an inability to use, or restrictions on the use of, the ingredients or a requirement for remedial action, which could cause Kenvue to incur significant additional costs, particularly if Kenvue needs or otherwise decides to reformulate the affected products, or result in litigation. . . .
>
> If Kenvue removes certain ingredients from its products, either voluntarily or pursuant to a regulatory mandate, Kenvue may not be able to successfully develop an alternative formulation or obtain necessary regulatory approvals on a timely basis, or at all. Furthermore, any reformulated product Kenvue introduces to the market may not be positively received by consumers and customers, which could result in lost sales, damage Kenvue's reputation or brands or otherwise adversely affect Kenvue's business, results of

operations or financial condition.

> Moreover, negative perceptions of Kenvue's products or their ingredients may arise from product liability claims, product recalls or product withdrawals, regardless of whether the claims, recalls or withdrawals directly involve Kenvue or its products. In addition, the mere publication of information asserting concerns about the reliability, safety or efficacy of competing products or ingredients in competing products that are also used in Kenvue's products could adversely affect Kenvue's business, results of operations or financial condition. Increased regulation, litigation or adverse publicity concerning ingredients used in Kenvue's products, such as acetaminophen, may discourage consumers from buying Kenvue's products that contain those ingredients, even when the regulation, litigation or publicity does not directly relate to or expressly mention Kenvue or its products, and even if not accurate. In addition, ***Kenvue believes its products are reliable, safe and effective when used for their intended purposes in accordance with label directions***. However, consumers have misused, and may in the future misuse, Kenvue's products, including for unauthorized, nefarious or other unintended purposes, which in certain instances has had, and may in the future have, serious or even fatal implications. Misuse of Kenvue's products has led to, and may in the future lead to, criticism on digital and social media platforms, negative coverage by traditional media and other forms of adverse publicity regarding Kenvue's products or their ingredients, which could similarly discourage consumers from buying Kenvue's products or otherwise adversely affect Kenvue's reputation or brands.

137. The foregoing statements in ¶136 were materially false and/or misleading because they failed to disclose, *inter alia*, the following adverse facts that existed at the time of the Johnson & Johnson Exchange Offer:

(a) Substantial concerns had been raised about the effectiveness of products containing PE for more than a decade, and those concerns proved to be well-founded;

(b) Between 2007 and 2023, multiple well-designed studies and clinical trials involving large numbers of patients demonstrated that oral PE is

ineffective at relieving symptoms of sinus and nasal congestion. These studies and trials included studies in allergic rhinitis by Horak 2009 and Day 2009, trials in subjects with seasonal allergic rhinitis by Meltzer 2015 and Meltzer 2016, and in the common cold, a Johnson & Johnson sponsored trial during the 2017-2018 cold season;

(c) In November 2015, two University of Florida professors submitted a citizen petition to the FDA asking the FDA to issue a final rule removing oral PE from the Final Monograph for OTC nasal decongestant drugs and citing four studies demonstrating, *inter alia*, that PE "is no more effective than placebo in decreasing nasal congestions and increasing the dose fourfold did not provide additional benefit";

(d) In May 2022, the professors submitted a supplement to their November 2015 citizen petition, citing three additional studies, including two studies sponsored by Johnson & Johnson, one of which suggested that "doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant";

(e) In June 2022, the American College of Clinical Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition stating that oral PE "is ineffective at the doses employed in current over-the-counter (OTC) products available in the United States" and explaining that due to PE's "poor bioavailability, sufficient phenylephrine concentrations never reach the patient's systemic circulation. Hence, consumers are regularly purchasing FDA-approved products that clearly don't work";

(f) In July 2022, the American Association of Colleges of Pharmacy submitted a comment to the FDA in support of the November 2015

citizen petition and requested the FDA to take action to remove oral PE from the OTC market in the United States, explaining that "[s]olid evidence exists and has been submitted to the FDA to support this action";

(g) On or before March 3, 2023, the FDA announced a meeting of the NDAC for April 12, 2023 to "discuss the adequacy of efficacy data available for oral phenylephrine as a nasal decongestant and whether oral nasal decongestants phenylephrine hydrochloride and phenylephrine bitartrate should be reclassified as not 'Generally Recognized as Safe and Effective' (GRASE) due to lack of efficacy";

(h) Roughly six weeks before the Kenvue IPO, on March 21, 2023, the FDA announced that this meeting would be postponed to a later unspecified date;

(i) On July 12, 2023, the FDA announced that the forthcoming public advisory meeting of the NDAC to discuss the efficacy of oral PE was to be held on September 11 and 12, 2023;

(j) As a result of the foregoing, Kenvue's asserted belief that its products "are reliable, safe and effective when used for their intended purposes in accordance with label directions" lacked a reasonable basis, at least with respect to Kenvue's products containing oral PE as an ingredient to treat sinus and nasal congestion, and Defendants' statement failed to disclose facts that seriously undermined the supposed basis for Kenvue's asserted belief;

(k) As a result of the foregoing, regulatory action by the FDA and its NDAC panel was probable and imminent, and the failure to disclose the pendency of these proceedings and the underlying studies demonstrating the ineffectiveness of oral PE caused investors to

materially underestimate the risks that Kenvue faced with respect to its products containing PE as an ingredient; and

(l) Defendants' statement that "[c]oncerns about the reliability, safety or efficacy of our products . . . have resulted, and could in the future result, in governmental investigations, regulatory action . . . , private claims and lawsuits, . . . [or] declining sales or reputational damage" was materially misleading because it failed to disclose that significant regulatory proceedings under the new OTC monograph had already been initiated by the FDA with respect to the efficacy of oral PE. Therefore, the risk of regulatory action with respect to oral PE, including the risk that there would be a determination that oral PE was not effective, was substantially heightened, and Defendants' statement failed to disclose material facts necessary to appreciate the magnitude of the risk.

138. The Exchange Offer Registration Statement and the Exchange Offer Prospectus touted the strength of the Company's brands and the efficacy of its products. While the Exchange Offer Registration Statement and the Exchange Offer Prospectus made no mention of phenylephrine (or PE) by name, they did make the following statement about Kenvue's full line of Tylenol products, which includes Tylenol products containing PE:

> Tylenol is the #1 global Pain brand and the #2 global Self Care brand, with the #1 U.S. household penetration. Tylenol has been caring for families since 1955 when its first product, Children's Elixir, was launched. Although the Tylenol story started with just one product, it has evolved to include a full suite of pain relief, cold and flu, sleep and pediatric products. ***Studies sponsored by Johnson & Johnson Consumer Inc. and by third parties have shown that these products help relieve, among other things***, headache and muscle pain, arthritis pain, ***sinus and nasal congestion***, fever and pain with sleeplessness. Kenvue is continuously looking for ways to expand Tylenol's brand

> leadership, particularly through Kenvue's digital and connected health offerings. For example, in 2022 Kenvue launched the Tylenol SmartCheck Digital Ear Scope, which empowers consumers to work with their healthcare providers to check for ear infections remotely, avoiding costly and time-consuming in-person visits.

139. The foregoing statements in ¶138 were materially false and/or misleading because they failed to disclose, *inter alia*, the following adverse facts that existed at the time of the Johnson & Johnson Exchange Offer:

(a) Substantial concerns had been raised about the effectiveness of products containing PE for more than a decade, and those concerns proved to be well-founded;

(b) Between 2007 and 2023, multiple well-designed studies and clinical trials involving large numbers of patients demonstrated that oral PE is ineffective at relieving symptoms of sinus and nasal congestion. These studies and trials included studies in allergic rhinitis by Horak 2009 and Day 2009, trials in subjects with seasonal allergic rhinitis by Meltzer 2015, and Meltzer 2016, and in the common cold, a Johnson & Johnson sponsored trial during the 2017-2018 cold season;

(c) In November 2015, two University of Florida professors submitted a citizen petition to the FDA asking the FDA to issue a final rule removing oral PE from the Final Monograph for OTC nasal decongestant drugs and citing four studies demonstrating, *inter alia*, that PE "is no more effective than placebo in decreasing nasal congestions and increasing the dose fourfold did not provide additional benefit";

(d) In May 2022, the professors submitted a supplement to their November 2015 citizen petition, citing three additional studies, including two studies sponsored by Johnson & Johnson, one of which

suggested that "doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant";

(e) In June 2022, the American College of Clinical Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition stating that oral PE "is ineffective at the doses employed in current over-the-counter (OTC) products available in the United States" and explaining that due to PE's "poor bioavailability, sufficient phenylephrine concentrations never reach the patient's systemic circulation. Hence, consumers are regularly purchasing FDA-approved products that clearly don't work";

(f) In July 2022, the American Association of Colleges of Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition and requested the FDA to take action to remove oral PE from the OTC market in the United States, explaining that "[s]olid evidence exists and has been submitted to the FDA to support this action";

(g) On or before March 3, 2023, the FDA announced a meeting of the NDAC for April 12, 2023 to "discuss the adequacy of efficacy data available for oral phenylephrine as a nasal decongestant and whether oral nasal decongestants phenylephrine hydrochloride and phenylephrine bitartrate should be reclassified as not 'Generally Recognized as Safe and Effective' (GRASE) due to lack of efficacy";

(h) Roughly six weeks before the Kenvue IPO, on March 21, 2023, the FDA announced that this meeting would be postponed to a later unspecified date;

(i) On July 12, 2023, the FDA announced that the forthcoming public advisory meeting of the NDAC to discuss the efficacy of oral PE was

to be held on September 11 and 12, 2023;

(j) As a result of the foregoing, Defendants' statement that "[s]tudies sponsored by Johnson & Johnson . . . and by third parties have shown that these products help relieve . . . sinus and nasal congestion" was materially false and misleading and lacked a reasonable basis, at least with respect to Tylenol products containing PE, including Tylenol Sinus + Headache, Tylenol Sinus Severe, and Tylenol Cold + Flu products, and Defendants' statement failed to disclose facts that seriously undermined the veracity and basis of this statement; and

(k) As a result of the foregoing, regulatory action by the FDA and its NDAC panel was probable and imminent, and the failure to disclose the pendency of these proceedings and the underlying studies demonstrating the ineffectiveness of oral PE caused investors to materially underestimate the risks that Kenvue faced with respect to its products containing PE as an ingredient.

140. The Exchange Offer Registration Statement and the Exchange Offer Prospectus made the following statement concerning the FDA's OTC monograph system:

> In order to market and sell a new drug product in the United States, a manufacturer must (1) file a New Drug Application ("NDA") that shows the quality, safety and effectiveness of the new drug, (2) file an Abbreviated New Drug Application that demonstrates the equivalence of a generic product to another company's branded drug product or (3) comply with the FDA's monograph system. Most of Kenvue's OTC products marketed in the United States, including Aveeno Restorative Skin Therapy Itch Relief Balm, Neutrogena Invisible Daily Defense, Tylenol Dissolve Packs, certain of Kenvue's Listerine mouthwash products and certain products intended to treat acne or be used as sunscreen, including skin care products with SPF, are regulated pursuant to the FDA's monograph system. The monographs establish the conditions, such as active ingredients, uses (indications),

> doses, labeling and testing, under which an OTC drug is generally recognized as safe and effective and can be marketed without an NDA and FDA premarket approval. ***Products marketed under the OTC monograph system are required to conform to specific quality, formula and labeling requirements. OTC monograph products that do not comply with these standards can be deemed unapproved new drugs and can be required to be withdrawn from the market. The Over-the-Counter Monograph Safety, Innovation, and Reform Act, enacted in March 2020, is expected to introduce significant reform to the OTC monograph system, including by replacing the FDA's existing rulemaking process with an administrative order process for issuing, revising and amending OTC monographs***.

141. The foregoing statements in ¶140 were materially false and/or misleading because they failed to disclose, *inter alia*, the following adverse facts that existed at the time of the Johnson & Johnson Exchange Offer:

(a) Substantial concerns had been raised about the effectiveness of products containing PE for more than a decade, and those concerns proved to be well-founded;

(b) Between 2007 and 2023, multiple well-designed studies clinical trials involving large numbers of patients demonstrated that oral PE is ineffective at relieving symptoms of sinus and nasal congestion. These studies and trials included studies in allergic rhinitis by Horak 2009 and Day 2009, trials in subjects with seasonal allergic rhinitis by Meltzer 2015 and Meltzer 2016, and in the common cold, a Johnson & Johnson sponsored trial during the 2017-2018 cold season;

(c) In November 2015, two University of Florida professors submitted a citizen petition to the FDA asking the FDA to issue a final rule removing oral PE from the Final Monograph for OTC nasal decongestant drugs and citing four studies demonstrating, *inter alia*, that PE "is no more effective than placebo in decreasing nasal

congestions and increasing the dose fourfold did not provide additional benefit";

(d) In May 2022, the professors submitted a supplement to their November 2015 citizen petition, citing three additional studies, including two studies sponsored by Johnson & Johnson, one of which suggested that "doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant";

(e) In June 2022, the American College of Clinical Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition stating that oral PE "is ineffective at the doses employed in current over-the-counter (OTC) products available in the United States" and explaining that due to PE's "poor bioavailability, sufficient phenylephrine concentrations never reach the patient's systemic circulation. Hence, consumers are regularly purchasing FDA-approved products that clearly don't work";

(f) In July 2022, the American Association of Colleges of Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition and requested the FDA to take action to remove oral PE from the OTC market in the United States, explaining that "[s]olid evidence exists and has been submitted to the FDA to support this action";

(g) On or before March 3, 2023, the FDA announced a meeting of the NDAC for April 12, 2023 to "discuss the adequacy of efficacy data available for oral phenylephrine as a nasal decongestant and whether oral nasal decongestants phenylephrine hydrochloride and phenylephrine bitartrate should be reclassified as not 'Generally Recognized as Safe and Effective' (GRASE) due to lack of efficacy";

(h) Roughly six weeks before the Kenvue IPO, on March 21, 2023, the FDA announced that this meeting would be postponed to a later unspecified date;

(i) On July 12, 2023, the FDA announced that the forthcoming public advisory meeting of the NDAC to discuss the efficacy of oral PE was to be held on September 11 and 12, 2023;

(j) The forthcoming meeting convened by the FDA requesting that the NDAC review, discuss, and vote on the efficacy of oral PE as a nasal decongestant was to be one of the first test cases for the March 2020 law that overhauled the monograph system;

(k) As a result of the foregoing, Defendants' statements concerning the requirements of and reforms to the OTC monograph system were materially misleading because they failed to disclose that regulatory proceedings under the newly reformed monograph system had already been initiated with the express purpose of reconsidering the efficacy of oral PE as a nasal decongestant, that these proceedings were to be the first of their kind under the newly reformed system, and that these proceedings carried a high risk of a determination that oral PE was not effective;

(l) As a result of the foregoing, regulatory action by the FDA and its NDAC panel was probable and imminent, and the failure to disclose the pendency of these proceedings and the underlying studies demonstrating the ineffectiveness of oral PE caused investors to materially underestimate the risks that Kenvue faced with respect to its products containing PE as an ingredient.

142. Item 105 of Regulation S-K requires that offering documents "provide under the caption 'Risk Factors' a discussion of the material factors that make an

investment in the registrant or offering speculative or risky." 17 C.F.R. § 229.105(a). Item 105 further requires the offering documents to "[c]oncisely explain how each risk affects the registrant or the securities being offered." 17 C.F.R. § 229.105(b). The discussion of risk factors:

> must be specific to the particular company and its operations, and should explain how the risk affects the company and/or the securities being offered. Generic or boilerplate discussions do not tell the investors how the risks may affect their investment.

Statement of the Comm'n Regarding Disclosure of Year 2000 Issues and Consequences by Pub. Cos., Inv. Advisers, Inv. Cos., & Mun. Sec. Issuers, 1998 WL 425894, at *14 (July 29, 1998).

143. Here, Defendants failed to adequately disclose, and in fact did not disclose at all, in the "Risk Factors" section of the Exchange Offer Registration Statement and the Exchange Offer Prospectus, the risks to Kenvue's sales, revenue, prospects, reputation and potential liability in relation to its line of products containing oral PE as an ingredient to treat sinus or nasal congestion. While the Exchange Offer Registration Statement and the Exchange Offer Prospectus did disclose hypothetical risks concerning the safety, reliability or efficacy of Kenvue's general range of products (and specific disclosures concerning past or pending issues related to certain products other than its products containing PE),[32] they did not disclose any specific risks relating to Kenvue's products containing PE and they failed to disclose specific facts necessary for investors to understand the magnitude of the risk, including the FDA's initiation of regulatory proceedings, with requested input from the NDAC, concerning the

[32] Certain of Kenvue's Tylenol products contain both acetaminophen and PE, but the risk disclosure at issue only discussed risks related to safety concerns about acetaminophen, not risks related to efficacy concerns about PE.

efficacy of oral PE. These PE-specific risks were material to Kenvue's sales, revenue, prospects, reputation and potential liability, *see supra* at ¶115, and should have been disclosed.

C. CLASS ACTION ALLEGATIONS

144. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of the "Class," consisting of all persons and entities that (1) purchased or otherwise acquired shares of Kenvue common stock pursuant and/or traceable to the IPO Registration Statement and suffered compensable damages caused by Defendants' violations of Sections 11, 12(a)(2), and 15 of the Securities Act and/or (2) acquired shares of Kenvue common stock pursuant and/or traceable to the Exchange Offer Registration Statement and suffered compensable damages caused by Defendants' violations of Sections 11, 12(a)(2), and 15 of the Securities Act. Excluded from the Class are Defendants and their families, the officers and directors and affiliates of Defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

145. The members of the Class are so numerous that joinder is impracticable. Shares of Kenvue's common stock are actively traded on the NYSE, millions of shares were sold in the IPO, and J&J exchanged over 1 billion shares of Kenvue common stock as part of the Exchange Offer. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through discovery, Plaintiffs believe there are thousands of members in the Class. Record owners and other Class members may be identified from records procured from or maintained by the Company or its transfer agent and may be notified of the pendency of this action using a form of notice similar to that customarily used in securities class actions.

146. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members, including:

a. whether Defendants violated the Securities Act, as alleged herein;

b. whether the IPO and Exchange Offer Registration Statements issued by Defendants to the investing public omitted and/or misrepresented material information in violation of the Securities Act; and

c. whether and to what extent Class members have sustained damages, as well as the proper measure of damages.

147. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

148. Plaintiffs will fairly and adequately protect the interests of Class members and have retained counsel competent and experienced in securities class actions.

149. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it exceedingly difficult, if not impossible and impracticable, for Class members to individually redress the wrongs alleged. There will be no difficulty in managing this action as a class action.

VI. NO SAFE HARBOR

150. Defendants are liable for any false and misleading forward-looking statements made in connection with the IPO and the Exchange Offer. The safe harbor provision of §27A of the Securities Act, 15 U.S.C. §77z-2(b)(2)(D), specifically excludes those statements "made in connection with an initial public

offering," which includes all of the false and misleading statements made in connection with the IPO and the Exchange Offer alleged herein.

VII. CLAIMS FOR RELIEF

COUNT I
Violation Of Section 11 Of The Securities Act In Connection With the IPO Against Defendant Kenvue, The Officer Defendants, and The Underwriter Defendants

151. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

152. This Count is brought by Plaintiffs pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against Kenvue, the Officer Defendants, and the Underwriter Defendants. The defendants named in this Count are responsible for the contents and dissemination of the IPO Registration Statement; signed the IPO Registration Statement; and/or were senior employees, directors, or underwriters who are appropriate defendants in this Count. Plaintiffs do not claim that any of the defendants named in this Count engaged in intentional or reckless misconduct or acted with fraudulent intent.

153. The IPO Registration Statement was materially false and/or misleading, contained untrue statements of material fact, omitted to state other facts necessary to make the statements made therein not misleading, and/or omitted to state material facts required to be stated therein.

154. This claim is brought by Plaintiffs on their own behalf and on behalf of other members of the Class who purchased or acquired shares of Kenvue common stock pursuant to and/or traceable to the Company's IPO. Each Class Member with claims under this Count acquired his, her, or its shares pursuant to and/or traceable to, and in reliance on, the IPO Registration Statement.

155. Kenvue is the issuer of the shares of common stock through the IPO Registration Statement. As an issuer of securities to the public, Kenvue is strictly

liable to Plaintiffs and the Class for the misstatements and omissions.

156. The Officer Defendants each signed the IPO Registration Statement either personally or through an attorney-in-fact and/or caused its issuance. Each of the Officer Defendants had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the IPO Registration Statement. They had a duty to ensure that such statements were true and correct, that there were no omissions of material fact that would make the statements misleading, and that the IPO Registration Statement contained all facts required to be stated therein. By virtue of the Officer Defendants' failure to exercise reasonable care, the IPO Registration Statement contained material misstatements and/or omissions of material facts. Accordingly, the Officer Defendants are strictly liable to Plaintiffs and the Class.

157. Each of the Underwriter Defendants owed to the holders of the shares obtained through the IPO Registration Statement the duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the IPO Registration Statement. They had a duty to ensure that such statements were true and correct, that there were no omissions of material fact that would make the statements misleading, and that the IPO Registration Statement contained all facts required to be stated therein. By virtue of the Underwriter Defendants' failure to exercise reasonable care, the IPO Registration Statement contained material misstatements and/or omissions of material facts. Accordingly, the Underwriter Defendants are strictly liable to Plaintiffs and the Class.

158. The defendants named in this Count were responsible for the contents and dissemination of the IPO Registration Statement. None of the defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the IPO Registration Statement were true or that there was no omission of material facts necessary to

make the statements made therein not misleading or that there was no omission of facts required to be stated therein.

159. The defendants named in this Count issued and disseminated, caused to be issued and disseminated, and participated in the issuance and dissemination of, material misstatements and/or omissions to the investing public that were contained in the IPO Registration Statement, which misrepresented or failed to disclose, among other things, the facts set forth above. By reason of the conduct alleged herein, the above named defendants in this Count violated and/or controlled a person who violated Section 11 of the Securities Act.

160. At the times they obtained their shares of Kenvue, Plaintiffs and members of the Class did so without knowledge of the facts concerning the misstatements and omissions alleged herein.

161. This claim is brought within one year after discovery of the untrue statements and/or omissions in the IPO Registration Statement should have been made and/or corrected through the exercise of reasonable diligence, and within three years of the effective date of the IPO. It is therefore timely.

162. By reason of the foregoing, Plaintiffs and the other members of the Class are entitled to damages under Section 11 as measured by the provisions of Section 11(e), from the Defendants and each of them, jointly and severally.

COUNT II
Violation Of Section 12(a)(2) Of The Securities Act
In Connection With the IPO Against Defendant Kenvue,
The Officer Defendants, and The Underwriter Defendants

163. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

164. This Count is brought by Plaintiffs pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. §77l(a)(2), on behalf of the Class, against Kenvue, the Officer Defendants, and the Underwriter Defendants. The defendants named in

this Count are responsible for offering and/or selling Kenvue stock by means of the IPO Prospectus. Plaintiffs do not claim that any of the defendants named in this Count engaged in intentional or reckless misconduct or acted with fraudulent intent.

165. By means of the defective IPO Prospectus, the defendants named in this Count promoted, solicited, and sold the Company's common stock to Plaintiffs and other members of the Class. The defendants named in this Count actively solicited purchasers of stock for the IPO by, among other things, preparing, disseminating, and presenting to potential investors and otherwise eliciting investor participation in the IPO. As a result, the defendants named in this Count were "statutory sellers" for the purposes of Section 12(a)(2) of the 1933 Act. Additionally, Kenvue was a statutory seller under SEC Rule 159A, which provides that an issuer is a statutory seller for the purposes of Section 12(a)(2) regardless of the form of underwriting.

166. The Prospectus for the IPO contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above. The defendants named in this Count owed Plaintiffs and the other members of the Class who purchased shares of Kenvue common stock pursuant and/or traceable to the IPO Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the IPO Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus as set forth above.

167. Plaintiffs did not know, nor in the exercise of reasonable diligence could Plaintiffs have known, of the untruths and omissions contained in the IPO Prospectus at the time Plaintiffs acquired Kenvue common stock.

168. By reason of the conduct alleged herein, the defendants named in this Count violated Section 12(a)(2) of the Securities Act, 15 U.S.C. §77l(a)(2). As a direct and proximate result of such violations, Plaintiffs and the other members of the Class who purchased Kenvue common stock pursuant and/or traceable to the IPO Prospectus sustained substantial damages in connection with their purchases of the securities. Accordingly, Plaintiffs and the other members of the Class who hold the securities issued pursuant and/or traceable to the Prospectus have the right to rescind and recover the consideration paid for their securities, and hereby tender their securities to Defendants sued herein. Class members who have sold their securities seek damages to the extent permitted by law.

169. This claim is brought within one year after discovery of the untrue statements and/or omissions in the IPO that should have been made and/or corrected through the exercise of reasonable diligence, and within three years of the effective date of the IPO. It is therefore timely.

COUNT III
Violation Of Section 15 Of The Securities Act
In Connection With The IPO Against
The Officer Defendants And Defendant Johnson & Johnson

170. Plaintiffs repeat and reallege each and every allegation contained above, as if fully set forth herein.

171. This cause of action is brought pursuant to Section 15 of the Securities Act, 15 U.S.C. §77o, against all the Officer Defendants and Defendant Johnson & Johnson. Plaintiffs do not claim that any of the defendants named in this Count engaged in intentional or reckless misconduct or acted with fraudulent intent.

172. The Officer Defendants were controlling persons of Kenvue by virtue of their positions as senior officers of Kenvue and their ability to cause the Company to arrange and execute the IPO and disseminate the IPO Registration Statement and IPO Prospectus in connection therewith. Defendant Johnson &

Johnson was a controlling person of Kenvue by virtue of its status as controlling shareholder and its ability to arrange and execute the IPO and disseminate the IPO Registration Statement and IPO Prospectus in connection therewith.

173. The Officer Defendants and Defendant Johnson & Johnson were in positions to control and did control, the false and misleading statements and omissions contained in the IPO Registration Statement and IPO Prospectus.

174. None of the Officer Defendants or Defendant Johnson & Johnson made reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the IPO Registration Statement and IPO Prospectus were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged herein.

175. Plaintiffs and the Class have sustained damages. The value of the shares of Kenvue common stock has declined substantially due to the Securities Act violations alleged herein.

176. By reason of the above conduct, for which Kenvue is primarily liable, as set forth above, the Officer Defendants and Defendant Johnson & Johnson are jointly and severally liable with and to the same extent as Kenvue pursuant to Section 15 of the Securities Act.

177. Defendant Johnson & Johnson and the Officer Defendants were culpable participants in the violations of Sections 11 and 12(a)(2) of the Securities Act as alleged above, based on their having signed or authorized the signing of the IPO Registration Statement and/or having otherwise participated in the process which allowed the IPO to be successfully completed.

178. This claim is brought within one year after discovery of the untrue statements and/or omissions in the IPO Registration Statement and IPO Prospectus that should have been made and/or corrected through the exercise of reasonable

diligence, and within three years of the effective date of the IPO. It is therefore timely.

COUNT IV
Violation Of Section 11 Of The Securities Act
In Connection With the Exchange Offer Against
Defendant Kenvue And The Individual Defendants

179. Plaintiffs repeat and reallege each and every allegation contained above, as if fully set forth herein.

180. This Count is brought by Plaintiffs pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against Kenvue and the Individual Defendants. The defendants named in this Count are responsible for the contents and dissemination of the Exchange Offer Registration Statement; signed the Exchange Offer Registration Statement; and/or were senior employees, directors, or underwriters who are appropriate defendants in this Count. Plaintiffs do not claim that any of the defendants named in this Count engaged in intentional or reckless misconduct or acted with fraudulent intent.

181. The Exchange Offer Registration Statement was materially false and/or misleading, contained untrue statements of material fact, omitted to state other facts necessary to make the statements made therein not misleading, and/or omitted to state material facts required to be stated therein.

182. This claim is brought by Plaintiffs on their own behalf and on behalf of other members of the Class who acquired shares of Kenvue common stock pursuant and/or traceable to the Exchange Offer. Each Class Member with claims under this Count acquired his, her, or its shares pursuant to and/or traceable to, and in reliance on, the Exchange Offer Registration Statement.

183. Kenvue is the issuer of the shares of common stock through the Exchange Offer Registration Statement. As an issuer of securities to the public, Kenvue is strictly liable to Plaintiffs and the Class for the misstatements and

omissions.

184. The Officer Defendants each signed the Exchange Offer Registration Statement either personally or through an attorney-in-fact and/or caused its issuance. Each of the Officer Defendants had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Exchange Offer Registration Statement. They had a duty to ensure that such statements were true and correct, that there were no omissions of material fact that would make the statements misleading, and that the Exchange Offer Registration Statement contained all facts required to be stated therein. By virtue of the Officer Defendants' failure to exercise reasonable care, the Exchange Offer Registration Statement contained material misstatements and/or omissions of material facts. Accordingly, the Officer Defendants are strictly liable to Plaintiffs and the Class.

185. Each of the Underwriter Defendants owed to the holders of the shares obtained through the Exchange Offer Registration Statement the duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Exchange Offer Registration Statement. They had a duty to ensure that such statements were true and correct, that there were no omissions of material fact that would make the statements misleading, and that the Exchange Offer Registration Statement contained all facts required to be stated therein. By virtue of the Underwriter Defendants' failure to exercise reasonable care, the Exchange Offer Registration Statement contained material misstatements and/or omissions of material facts. Accordingly, the Underwriter Defendants are strictly liable to Plaintiffs and the Class.

186. The defendants named in this Count were responsible for the contents and dissemination of the Exchange Offer Registration Statement. None of the defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Exchange

Offer Registration Statement were true or that there was no omission of material facts necessary to make the statements made therein not misleading or that there was no omission of facts required to be stated therein.

187. The defendants named in this Count issued and disseminated, caused to be issued and disseminated, and participated in the issuance and dissemination of, material misstatements and/or omissions to the investing public that were contained in the Exchange Offer Registration Statement, which misrepresented or failed to disclose, among other things, the facts set forth above. By reason of the conduct alleged herein, the above named defendants in this Count violated and/or controlled a person who violated Section 11 of the Securities Act.

188. At the times they obtained their shares of Kenvue, Plaintiffs and members of the Class did so without knowledge of the facts concerning the misstatements and omissions alleged herein.

189. This claim is brought within one year after discovery of the untrue statements and/or omissions in the Exchange Offer Registration Statement should have been made and/or corrected through the exercise of reasonable diligence, and within three years of the effective date of the Exchange Offer. It is therefore timely.

190. By reason of the foregoing, Plaintiffs and the other members of the Class are entitled to damages under Section 11 as measured by the provisions of Section 11(e), from the Defendants and each of them, jointly and severally.

COUNT V
Violation Of Section 12(a)(2) Of The Securities Act
In Connection With the Exchange Offer Against
Defendant Kenvue, Defendant Johnson & Johnson,
And The Individual Defendants

191. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

192. This Count is brought by Plaintiffs pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. §77l(a)(2), on behalf of the Class, against Kenvue, the Officer Defendants, and the Underwriter Defendants. The defendants named in this Count are responsible for offering and/or selling Kenvue stock by means of the Exchange Offer Prospectus. Plaintiffs do not claim that any of the defendants named in this Count engaged in intentional or reckless misconduct or acted with fraudulent intent.

193. By means of the defective Exchange Offer Prospectus, the defendants named in this Count promoted, solicited, and sold the Company's common stock to Plaintiffs and other members of the Class. Defendants named in this Count actively solicited purchasers of stock for the Exchange Offer by, among other things, preparing, disseminating, and presenting to potential investors and otherwise eliciting investor participation in the Exchange Offer. As a result, the defendants named in this Count were "statutory sellers" for the purposes of Section 12(a)(2) of the 1933 Act. Additionally, Kenvue was a statutory seller under SEC Rule 159A, which provides that an issuer is a statutory seller for the purposes of Section 12(a)(2) regardless of the form of underwriting.

194. The Prospectus for the Exchange Offer contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above. The defendants named in this Count owed Plaintiffs and the other members of the Class who acquired shares of Kenvue common stock pursuant and/or traceable to the Exchange Offer Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Exchange Offer Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Exchange Offer Prospectus as

set forth above.

195. Plaintiffs did not know, nor in the exercise of reasonable diligence could Plaintiffs have known, of the untruths and omissions contained in the Exchange Offer Prospectus at the time Plaintiffs acquired Kenvue common stock.

196. By reason of the conduct alleged herein, the defendants named in this Count violated Section 12(a)(2) of the Securities Act, 15 U.S.C. §77l(a)(2). As a direct and proximate result of such violations, Plaintiffs and the other members of the Class who acquired Kenvue common stock pursuant and/or traceable to the Exchange Offer Prospectus sustained substantial damages in connection with their purchases of the securities. Accordingly, Plaintiffs and the other members of the Class who hold the securities issued pursuant and/or traceable to the Exchange Offer Prospectus have the right to rescind and recover the consideration paid for their securities, and hereby tender their securities to defendants sued herein. Class members who have sold their securities seek damages to the extent permitted by law.

197. This claim is brought within one year after discovery of the untrue statements and/or omissions in the Exchange Offer that should have been made and/or corrected through the exercise of reasonable diligence, and within three years of the effective date of the Exchange Offer. It is therefore timely.

COUNT VI
Violation Of Section 15 Of The Securities Act
In Connection With The Exchange Offer Against
The Individual Defendants And Defendant Johnson & Johnson

198. Plaintiffs repeat and reallege each and every allegation contained above, as if fully set forth herein.

199. This cause of action is brought pursuant to Section 15 of the Securities Act, 15 U.S.C. §77o, against all the Individual Defendants and Defendant Johnson & Johnson. Plaintiffs do not claim that any of the defendants named in this Count

engaged in intentional or reckless misconduct or acted with fraudulent intent.

200. The Individual Defendants were controlling persons of Kenvue by virtue of their positions as senior officers or directors of Kenvue and their ability to cause the Company to arrange and execute the Exchange Offer and disseminate the Exchange Offer Registration Statement and Exchange Offer Prospectus in connection therewith. Defendant Johnson & Johnson was a controlling person of Kenvue by virtue of its status as controlling shareholder and its ability to arrange and execute the Exchange Offer and disseminate the Exchange Offer Registration Statement and Exchange Offer Prospectus in connection therewith.

201. The Individual Defendants and Defendant Johnson & Johnson were in positions to control and did control, the false and misleading statements and omissions contained in the Exchange Offer Registration Statement and the Exchange Offer Prospectus.

202. None of the Individual Defendants or Defendant Johnson & Johnson made reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Exchange Offer Registration Statement and Exchange Offer were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged herein.

203. Plaintiffs and the Class have sustained damages. The value of the shares of Kenvue common stock has declined substantially due to the Securities Act violations alleged herein.

204. By reason of the above conduct, for which Kenvue is primarily liable, as set forth above, the Individual Defendants and Defendant Johnson & Johnson are jointly and severally liable with and to the same extent as Kenvue pursuant to Section 15 of the Securities Act.

205. Defendant Johnson & Johnson and the Individual Defendants were

culpable participants in the violations of Sections 11 and 12(a)(2) of the Securities Act as alleged above, based on their having signed or authorized the signing of the Exchange Offer Registration Statement and/or having otherwise participated in the process which allowed the Exchange Offer to be successfully completed.

206. This claim is brought within one year after discovery of the untrue statements and/or omissions in the Exchange Offer Registration Statement and Exchange Offer Prospectus that should have been made and/or corrected through the exercise of reasonable diligence, and within three years of the effective date of the Exchange Offer. It is therefore timely.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

(a) declaring the action to be a proper class action pursuant to Fed. R. Civ. P. 23;

(b) awarding damages in favor of Plaintiffs and all other Class members against all Defendants, jointly and severally, including interest thereon;

(c) awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorney's fees and expert fees; and

(d) awarding equitable, injunctive, and other relief as the Court may deem just and proper.

IX. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

DATED: March 12, 2024

Respectfully submitted,

CARELLA BYRNE CECCHI BRODY & AGNELLO, P.C.

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of March, 2024, a true and correct copy of the foregoing document was served by CM/ECF to the parties registered to the Court's CM/ECF system.

s/ James E. Cecchi
James E. Cecchi